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In The

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC. and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF ON THE MERITS FOR PETITIONER INWOOD LABORATORIES, INC.

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QUESTIONS PRESENTED

I. Whether the truthful, comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement.

II. Whether Section 32 of the Lanham Act [15 U.S.C. §1114] grants a trademark owner monopoly rights in the color of its product.

PARTIES TO THE PROCEEDING BELOW

The parties to the proceeding whose judgment is sought to be reviewed, in addition to Inwood Laboratories, Inc. ("Inwood"), are: Premo Pharmaceutical Laboratories, Inc. ("Premo"); Darby Drug Co., Inc. ("Darby"); MD Pharmaceutical Company, Inc. ("MD"); Rugby Laboratories, Inc. ("Rugby"); and Sherry Pharmaceutical Co., Inc. ("Sherry"). Those petitioners are filing separate briefs with this Court. Supreme Court Rule 34.1(b). Additionally, as required by Supreme Court Rule 28.1, Inwood listed its corporate affiliations in its petition for *certiorari*. Said listing is currently accurate.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
PARTIES TO THE PROCEEDING BELOW	ii
TABLE OF CONTENTS	iii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
JURISDICTION	2
CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED	2
STATEMENT OF THE CASE	3
Introduction	3
Parties Hereto and the Nature of their Business	4
The Impact of Drug Substitution Laws	7
The Course of Proceedings Below	9
The "Additional Evidence" Produced By Ives	14
The Role of Capsule Colors for Prescription Drugs	17
The Ruling of the District Court After Trial	23
SUMMARY OF ARGUMENT	24

Contents

Page

ARGUMENT:

I. THE TRUTHFUL COMPARATIVE USE OF A TRADEMARK IN LABELING AND ADVERTISING FORMS NO LEGAL BASIS FOR A FINDING OF TRADEMARK INFRINGEMENT OR CONTRIBUTORY TRADEMARK INFRINGEMENT. 26

A. THE IVES IV MAJORITY OPINION ERRED IN ASSUMING THAT PHARMACISTS HAD COMMITTED TRADEMARK INFRINGEMENT 26

B. THE IVES IV OPINION ERRONEOUSLY APPLIED THE DOCTRINE OF CONTRIBUTORY TRADEMARK INFRINGEMENT AND IN SO DOING INTERFERED WITH PETITIONERS' EXERCISE OF THEIR FIRST AMENDMENT RIGHT TO FREE SPEECH. 32

II. SECTION 32 OF THE LANHAM ACT MAY NOT GRANT A TRADEMARK OWNER MONOPOLY RIGHTS IN THE COLOR OF ITS PRODUCT 41

CONCLUSION 47

TABLE OF AUTHORITIES

Cases Cited:

Abbott Laboratories v. Celebrezze, 228 F.Supp. 855 (D.Del. 1964), *vacated on other grounds,* 352 F.2d 286 (3d Cir. 1965) 4

A.H. Robins Co. v. Medicine Chest Corp., 206 U.S.P.Q. 1015 (E.D.Mo. 1980) 5

A. Leschen & Sons Rope Co. v. Broderick & Bascom Rope Co., 201 U.S. 166 (1906) 41

American Safety Table Co. v. Schreiber, 269 F.2d 255 (2d Cir.), *cert. denied,* 361 U.S. 915 (1959) 42

Amstar Corp. v. Domino's Pizza, Inc., 615 F.2d 252 (5th Cir.), *cert. denied,* 449 U.S. 899 (1980) 27

Andrew Jurgens Co. v. Bonded Products Corp., 21 F.2d 419 (2d Cir. 1927), *cert. denied,* 275 U.S. 572 (1928) 32

Application of Deister Concentrator Co., 289 F.2d 496 (CCPA 1961) 44

Application of E.I.DuPont & De Nemours & Co., 476 F.2d 1357 (CCPA 1973) 31

Bates v. State Bar of Arizona, 433 U.S. 350 (1977) 39

Bayer Co. v. United Drug Co., 272 F. 505 (S.D.N.Y. 1921) . 29

Contents

Page

Biocraft Laboratories, Inc. v. Merck & Co., Inc., ___ F.Supp. ___, Civ. Action No. 77-693 (D.N.J. Oct. 2, 1980). . 21, 42

Bliss v. Gotham Industries, Inc., 316 F.2d 848 (9th Cir. 1963) . 44

Boeringer-Ingelheim GmbH v. Pharmadyne Laboratories, 211 U.S.P.Q. 1163 (D.N.J. 1980) 42

Boots Co. Ltd. v. Approved Prescription Services, Ltd., [1980] ___ Ch. ___, B.No. 140 (Unreported: Martin Meredith) (Ch. Div'l. Ct. March 6, 1980), *aff'd*, [1980] B. No. 140 (Unreported: Association) (Court of Appeal Civ. Div. March 28, 1980) 21, 22

Campbell Soup Co. v. Armour & Co., 175 F.2d 795 (3d Cir.), *cert. denied*, 338 U.S. 847 (1949) 41

Champion Spark Plug Co. v. Sanders, 331 U.S. 125 (1947) . 28

Coats v. Merrick Thread Co., 149 U.S. 562 (1893) 41

Coca-Cola Co. v. Dorris, 311 F. Supp. 287 (E.D.Ark. 1970) . 28

Coca-Cola Co. v. Snow Crest Beverages, 64 F.Supp. 980 (D.Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947) 33, 34, 38

Coca-Cola Co. v. The Koke Company of America, 254 U.S. 143 (1920) 38, 41

Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964) 34, 41, 44, 46

Contents

Page

Corning Glass Works v. Jeanette Glass Co., 308 F.Supp. 1321 (S.D.N.Y.), *aff'd per curiam*, 432 F.2d 784 (2d Cir. 1970) . 32

Cuervo v. Jacob Henkell Co., 50 F. 471 (S.D.N.Y. 1892).. 32

Diamond Match Co. v. Saginaw Match Co., 142 F. 727 (6th Cir. 1906), *cert. denied*, 213 U.S. 598 (1908) 41

DuPont Cellophane Co. v. Waxed Products Co., 85 F.2d 75 (2d Cir.), *cert. denied*, 299 U.S. 601 (1936) 30

Electric Auto-Lite Co. v. P&D Mfg. Co., 78 F.2d 700 (2d Cir.), *cert. denied*, 296 U.S. 648 (1935) 28

Famolare, Inc. v. Melville Corp., 472 F.Supp. 738 (D.Haw. 1979), *aff'd without opinion*, 652 F.2d 62 (9th Cir. 1981) 34, 39, 40

Fortnightly Corp. v. United Artists Television, Inc., 392 U.S. 390 (1968) 39

Fur Information and Fashion Council, Inc. v. E.F. Timme & Son, Inc., 364 F.Supp. 16 (S.D.N.Y. 1973), *aff'd on other grounds*, 501 F.2d 1048 (2d Cir.), *cert. denied*, 419 U.S. 1022 (1974) 40

Geisel v. Poynter Products, 295 F.Supp. 331 (S.D.N.Y. 1968) 28

Goland v. CIA, 607 F.2d 339 (D.C.Cir. 1978), *cert. denied*, 445 U.S. 927 (1980) 35

Contents

Page

Goldstein v. California, 412 U.S. 546 (1973) 46

Heide v. Wallace & Co., 129 F. 649 (D.N.J. 1904), *aff'd*, 135 F. 346 (3d Cir. 1905) 6

Henry v. A.B. Dick Co., 224 U.S. 1 (1912) 39

Hoffman-La Roche v. Premo Pharmaceutical Laboratories, Inc., 210 U.S.P.Q. 374 (D.N.J 1980) 42

Howard Dustless Duster Co. v. Carleton, 219 F. 913 (D.Conn. 1915) 39

International Order of Job's Daughters v. Lindeburg & Co., 633 F.2d 912 (9th Cir. 1980), *cert. denied*, ___ U.S. ___, 69 L.Ed.2d 956 (1981) 41

Ives Laboratories, Inc. v. Bioline Laboratories, Inc., et. al., Civ. Action No. 81-914 (D.N.J., Complaint filed Mar. 3, 1981) 23

Ives Laboratories, Inc. v. Darby Drug Co., Inc. [Ives I], 455 F. Supp. 939 (E.D.N.Y. 1978) 1, 12, 34

Ives Laboratories, Inc. v. Darby Drug Co., Inc., [Ives II] 601 F.2d 631 (2d Cir. 1979) .....
... 1, 5, 9, 10, 12, 13, 14, 16, 23, 24, 26, 33, 34, 35, 45, 46

Ives Laboratories, Inc. v. Darby Drug Co., Inc. [Ives III], 488 F. Supp. 394 (E.D.N.Y. 1980) .....
..... 2, 4, 5, 12, 16, 19, 20, 23, 29, 33, 35, 47

Contents

Page

Ives Laboratories, Inc. v. Darby Drug Co., Inc. [Ives IV], 638 F.2d 538 (2d Cir. 1981) 2, 3, 8, 10, 12, 14, 15, 16, 26, 28, 31, 32, 33, 35, 36, 37, 41, 46

Ives Laboratories, Inc. v. Darby Drug Co., Inc. [Ives V], ___ F.Supp. ___ No. 78C372 (E.D.N.Y. May 12, 1981) . 41

J.C. Penney Co. v. H.D. Lee Mercantile Co., 120 F.2d 949 (8th Cir. 1941) 44

Jellibeans, Inc. v. Skating Clubs of Georgia, Inc., ___ F. Supp. ___ No. C-80-1689A (N.D. Ga. May 19, 1981), reported in 540 BNA Patent, Trademark & Copyright Journal, A-5 (August 6, 1981) 43

John B. Stetson Co. v. Stephen L. Stetson Co., 14 F.Supp. 74 (S.D.N.Y.), *modified*, 85 F.2d 586 (2d Cir.), *cert. denied*, 299 U.S. 605 (1936) 26, 32

Johnson & Johnson v. Quality Pure Mfg. Co., 484 F.Supp. 975 (D.N.J. 1979) 42

Keene Corp. v. Paraflex Industries, Inc., 653 F.2d 822 (3d Cir. 1981) 41, 44

Kellogg Co. v. National Biscuit Co., 305 U.S. 111 (1938) 41, 42, 45, 46

Kewanee Oil Corp. v. Bicron Corp., 416 U.S. 470 (1974).. 46

L.E. Waterman Co., 34 App.D.C. 185 (D.C.Cir. 1909) ... 41

Page

Marion Laboratories, Inc. v. Michigan Pharmacal Corp., 338 F.Supp. 762 (E.D.Mich. 1972), *aff'd without opinion*, 473 F.2d 910 (6th Cir. 1973) 23

Martin H. Smith Co. v. American Pharmaceutical Co., 270 N.Y. 184 (1936) 37

Mattel, Inc. v. Goldberger Doll Mfg. Co., Inc., 200 F.Supp. 517 (E.D.N.Y. 1961) 34

Mead Johnson & Co. v. Premo Pharmaceutical Laboratories, Inc., 207 U.S.P.Q. 820 (D.N.J. 1980) 10

Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc., 194 U.S.P.Q. 157 (D.N.J. 1977), *aff'd on procedural grounds*, 579 F.2d 786 (3d Cir. 1978) 11, 12, 42

Newcomer & Lewis v. J.A. Scriven Co., 168 F. 621 (6th Cir.), *cert. denied*, 214 U.S. 518 (1909) 41

Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960)..21, 41, 44

Nugrape Co. of America v. Glazier, 22 F.2d 596 (5th Cir. 1927) 33

Pagliero v. Wallace China Co., 198 F.2d 339 (9th Cir. 1952) 23, 44

Pennwalt Corp. v. Zenith Laboratories, Inc., 472 F.Supp. 413 (E.D.Mich. 1979), *appeal dismissed*, 615 F.2d 1362 (6th Cir. 1980) 13, 45

Contents

Page

Pezon et Michel v. Ernest R. Hewin Associates, Inc., 270 F.Supp. 423 (S.D.N.Y. 1967) 34

Pfizer & Co. v. Generic Formulae, Inc., 275 F.Supp. 421 (E.D.N.Y. 1967) 29

Pharmaceutical Mfrs. Ass'n v. Kennedy, 471 F.Supp. 1224 (D.Md. 1979) 9

Pharmaceutical Mfrs. Ass'n v. Whelan, ___ Misc.2d ___, Index No. 15831/78 (Sup.Ct.N.Y.Co., Aug. 15, 1980), *aff'd without opinion*, 79 A.D.2d 876, 435 N.Y.S.2d 618 (1st Dept., Dec. 4, 1980), *appeal pending* 9

Pharmaceutical Society of New York, Inc. v. Lefkowitz, 586 F.2d 953 (2d Cir. 1978) 9

Pignons S.A. De Mecanique De Precision v. Polaroid Corp., 657 F.2d 482 (1st Cir. 1981) 27

Plastilite Corp. v. Kassnar Imports, 508 F.2d 824 (CCPA 1975) 41

Prestonettes, Inc. v. Coty, 264 U.S. 359 (1924) 28

Reid, Murdoch & Co. v. H.P. Coffee Co., 48 F.2d 817 (8th Cir.), cert. denied, 284 U.S. 621 (1931) 26

Rice-Stix Dry Goods Co. v. J.A. Scriven Co., 165 F. 621 (6th Cir. 1908), *cert. denied*, 223 U.S. 708 (1911) 41

Roche Products Ltd. v. Berk Pharmaceuticals, Ltd., [1973] RPC 473 (Supreme Court of Judicature) 22

Contents

Page

Rosemont Enterprises, Inc. v. Random House, Inc., 366 F.2d 303 (2d Cir. 1966), *cert. denied*, 385 U.S. 1009 (1967).. 40

Ross-Whitney Corp. v. Smith, Kline & French Laboratories, 207 F.2d 190 (9th Cir. 1953) 37

Samson Cordage Works v. Puritan Cordage Mills, 211 F. 603 (6th Cir. 1914) 41

Saxlehner v. Wagner, 216 U.S. 375 (1910) 27, 28, 40

Schlitz Brewing Co. v. Houston Ice Co., 250 U.S. 28 (1919) 41

Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964).. ..... 34, 41, 44, 46

Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169 (1896) .. 46

SK&F Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055 (3d Cir. 1980), *aff'g* 481 F.Supp. 1184 (D.N.J. 1979) 42

Smith, Kline & French Laboratories v. Broder, 125 U.S.P.Q. 299 (S.D. Tex. 1959) 37

Smith, Kline & French Laboratories v. Clark & Clark, 157 F.2d 725 (3d Cir.), *cert. denied*, 329 U.S. 796 (1946).. ..... 34, 41, 44, 45

Smith, Kline & French Laboratories v. Heart Pharmaceutical Corp., 90 F.Supp. 976 (S.D.N.Y. 1950) 37

Contents

Page

Smith, Kline & French Laboratories v. Waldman, 69 F.Supp. 646 (E.D.Pa. 1946) 33, 44

Smith v. Chanel, Inc., 402 F.2d 562 (9th Cir. 1968) 28

Societe Comptoir de L'Indus., etc. v. Alexander's Dept. Stores, 299 F.2d 33 (2d Cir. 1962) 28

Stix Products, Inc. v. United Merchants & Mfrs., Inc., 295 F.Supp. 479 (S.D.N.Y.1968) 26, 33

Stop the Olympic Prison v. U.S. Olympic Committee, 489 F.Supp. 1112 (S.D.N.Y. 1980) 40

Swank, Inc. v. Anson, Inc., 196 F.2d 330 (1st Cir. 1952).. 34

Syntex Laboratories, Inc. v. Norwich Pharmacal Co., 315 F.Supp. 45 (S.D.N.Y. 1970), *aff'd,* 437 F.2d 566 (2d Cir. 1971) 29

Tast-T-Nut Co. v. Variety Nut & Date Co., 245 F.2d 3 (6th Cir. 1957) 41

Taylor Instrument Companies v. Fawley-Brost Co., 139 F.2d 98 (7th Cir. 1943), *cert. denied,* 321 U.S. 785 (1944).. 28

Time, Inc. v. Bernard Geis Associates, 293 F.Supp. 130 (S.D.N.Y. 1968) 40

Triangle Publications, Inc. v. Knight-Ridder Newspapers, Inc., 445 F.Supp. 875 (S.D. Fla. 1978), *aff'd on other grounds,* 626 F.2d 1171 (5th Cir. 1980) 40

Contents

Page

Unistrut Corp. v. Power, 280 F.2d 18 (1st Cir. 1960) 41

United States v. Ciba-Geigy Corp., 508 F.Supp. 1118 (D.N.J. 1976) 5

United States v. Lowell, 649 F.2d 950 (3d Cir. 1981) 35

Universal City Studios, Inc. v. Sony Corp. of America, 659 F.2d 963 (9th Cir. 1981) 39

Upjohn Co. v. Schwartz, 246 F.2d 254 (2d Cir. 1957) 37, 41, 44, 45

Viavi Co. v. Vimedia Co., 245 F. 289 (8th Cir. 1917), *cert. denied*, 246 U.S. 664 (1918) 28, 41

Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976) 39

Warner-Lambert Co. v. FTC, 562 F.2d 749 (D.C.Cir. 1977), *cert. denied*, 435 U.S. 750 (1978) 21

Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609 (1973) 10, 21

William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526 (1924) 33, 41, 44, 45

Zangerle & Peterson Co. v. Venice Furniture Novelty Mfg. Co., 133 F.2d 266 (7th Cir. 1943) 32, 34, 41, 46

Contents *Page*

Statutes and Regulations Cited:

15 U.S.C. §1114 ..... passim

15 U.S.C. §1125(a) 3, 12, 13, 23, 34, 42

28 U.S.C. §1254(1) 2

28 U.S.C. §2101(c) 2

35 U.S.C. §271(b) 39

MICH. COMP. LAWS ANN. §338.1114a (Supp. 1975-76).. 13

MICH. COMP. LAWS ANN. §338.1114a(3)(b) (Supp. 1975-76) 13

N.Y. EDUCATION LAW §6810 (McKinney's Supp. 1981).. ..... 3, 8

N.Y. EDUCATION LAW §6815(2)(h) (McKinney's Supp. 1981) 3, 8

N.Y. EDUCATION LAW §6815(2)(j) (McKinney's Supp. 1981) 3, 8

N.Y. EDUCATION LAW §6816 (McKinney's Supp. 1981).. ..... 3, 8

N.Y. EDUCATION LAW §6816-a (McKinney's Supp. 1981). 3, 8

Contents

Page

N.Y. GEN. BUS. LAW §368-d (McKinney's 1968) 12

N.Y. PUBLIC HEALTH LAW §206(1)(o) (McKinney's Supp. 1981) 3

21 C.F.R. §200.7 (1981) 4

United States Constitution Cited:

Article I, §8, Clause 8 2

First Amendment 2, 25, 32, 40

Rule Cited:

F.R.Civ.P. 60(b) 35

Other Authorities Cited:

Annotation, *What Constitutes In Commerce Within Meaning of §32(1)(a) of Lanham Trade-Mark Act*, 15 ALR Fed 368 (1973) 30

20 APhARMACY WEEKLY (November 4, 1981) 35

R. Bond and D. Lean, SALES, PROMOTION AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS (1977) 7

3R Callman, UNFAIR COMPETITION §82.1(m) (Supp. 1980) 21, 29, 39, 43, 44

Contents

Page

Comment, *Product Simulation in the Eighth Circuit*, 57 NEB. L.REV. 91 (1978) 24, 42

Competition in the Drug Industry: Hearings Before the Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce (97th Cong., 1st Sess., Mar. 10, 1981) 6

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DRUG PRODUCT SELECTION, STAFF REPORT TO THE FEDERAL TRADE COMMISSION (Bureau of Consumer Protection, Jan. 1979) 6, 9

FDA Drug List: Key to Generic Substitution, FDA CONSUMER (Feb. 1979) 8

1 Gilson, TRADEMARK PROTECTION AND PRACTICE, (1980) 26

Page

C.W. Gowdy, J.T. Hamilton and R.B. Philip, *A Controlled Clinical Trial Using Placebos in Normal Subjects: A Teaching Exercise,* 96 CAN.MED.ASS'N J. 1317 (1967) . 21

Haddad, *Generic Drugs — Tomorrow's Market,* 33 FOOD, DRUG & COSM.L.J. 488 (1978) 9

A. Leslie, *Ethics and Practice of Placebo Therapy,* 16 AM. J.MED. 854 (1954) 21

J.T. McCarthy, TRADEMARKS AND UNFAIR COMPETITION (1973) 27, 28, 30, 39

1-Part 2 MOORE'S FEDERAL PRACTICE (2d Ed. 1979) 18

National Association of Board of Pharmacy Survey of Pharmacy Law (1981-82) 8

Note, *Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws,* 67 KY.L.J. 384 (1978-79) 4, 7, 8

Note, *Improving Michigan's Generic Drug Law,* 9 MICH. J.L. REFORM 394 (1976) 13

Note, *Pharmaceutical Trademarks,* 15 TULSA L.J. 327 (1979) 6

Note, *Unfair Competition and the Doctrine of Functionality,* 64 COLUM. L. REV. 544 (1964) 38, 45

Contents

Page

Prescription Drug Labeling and Price Advertising, Hearings Before the Subcomm. on Consumer Protection and Finance for the House Comm. on Interstate and Foreign Commerce (94th Cong., 2nd Sess. April 22, 1976) 22, 23

Report of New York State Assembly Office of Legislative Oversight and Analysis, *Are Generics Safe?* (June 23, 1978) 6

RESTATEMENT OF TORTS, §742 (1938) 45

Schapira, et al., *Study on the Effects of Tablet Colour in the Treatment of Anxiety States* (1970) BRIT. MED J. 2:446 . 21

A. Seidel, S. Dubroff, and E. Gonda, TRADEMARK LAW AND PRACTICE (1963) 29

SRI International, *Pharmaceutical Industry Perspectives: A U.S. Generics Breakthrough?* (May 1980) 9

Stern, *The Persantine, Librax & Elavil Decisions: Colourful Brands of Drugs,* 2 EUR. INTEL. PROP. REV. 59 (1981) . 43

Stern & Hoffman, *Public Injury and the Public Interest: Secondary Meaning in the Law of Unfair Competition,* 110 U.PA.L.REV. 935 (1962) 42

D.S. Trouton, *Placebos and Their Pschycological Effect,* 103 J.MENTAL SCI., 344 (1957) 21

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INDEX TO APPENDICES TO THE PETITION FOR CERTIORARI

For the convenience of the Court, the appendices to Inwood's petition for *certiorari* are listed below.

		Page
Appendix A -	Opinion of the United States District Court for the Eastern District of New York, *Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 455 F.Supp. 939 (E.D.N.Y. 1979)	1a
Appendix B -	Opinion of the United States Court of Appeals for the Second Circuit, *Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 601 F.2d 631 (2d Cir. 1979)	28a
Appendix C -	Opinion of the United States District Court for the Eastern District of New York, *Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 488 F.Supp. 394 (E.D.N.Y. 1980)	56a
Appendix D -	Opinion of the United States Court of Appeals for the Second Circuit, *Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 638 F.2d 538 (2d Cir. 1981)	71a
Appendix E -	Order of the United States Court of Appeals for the Second Circuit, *Ives Laboratories, Inc. v. Darby Drug Co., Inc.* (2d Cir., Feb. 25, 1981)	94a

		Page
Appendix F -	Memorandum and Order of the United States District Court for the Eastern District of New York, ____ F.Supp. ____, No. 78 C 372 (E.D.N.Y., May 12, 1981)	96a
Appendix G -	Article I, §8, clause 8 of the Constitution of the United States	105a
	First Amendment to the Constitution of the United States	106a
	§32 of the Lanham Act, 15 U.S.C. §1114	107a
	§43(a) of the Lanham Act, 15 U.S.C. §1125(a)	110a
	New York Education Law, §§6810; 6815(2)(h), (j); 6816; 6816-a (McKinney's Supp. 1981)	112a-120a
	New York Public Health Law, §206(1)(o) (McKinney's Supp. 1981)	121a

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BRIEF ON THE MERITS FOR PETITIONER INWOOD LABORATORIES, INC.

OPINIONS BELOW

For convenience, the five opinions rendered below were reprinted in the Appendices to the Petition for *Certiorari* ("Pet.App.") in chronological order.

The first opinion of the District Court, denying respondent's request for preliminary injunctive relief on its primary claims, is officially reported at 455 F.Supp. 939 (E.D.N.Y. 1978), and reprinted in Pet.App. A at 1a-27a (hereinafter referred to as "*Ives* I"). The Court of Appeals' decision, affirming the District Court's denial of preliminary injunctive relief, is officially reported at 601 F.2d 631 (2d Cir. 1979), and reprinted in Pet.App. B at 28a-53a (hereinafter "*Ives* II").

The second opinion of the District Court, dismissing respondent's complaint, is officially reported at 488 F.Supp. 394 (E.D.N.Y. 1980), and reprinted in Pet.App. C at 54a-70a (hereinafter "*Ives* III"). The opinion of the Court of Appeals at issue herein, reversing the District Court, is officially reported at 638 F.2d 538 (2d Cir. 1981), and reprinted in Pet.App. D at 71a-93a (hereinafter "*Ives* IV"). A subsequent order by the Court of Appeals denied petitioners' timely petition for rehearing or rehearing *en banc* without opinion on February 25, 1981. The order is not officially reported, and a copy of this order is reprinted in Pet.App. E at 94a-95a. Acting on the mandate of the Court of Appeals, on May 12, 1981, the District Court entered an order which, *inter alia*, enjoined petitioners from marketing a drug product in the same capsule colors as those sold by respondent. The memorandum and order are not yet officially reported, and copies thereof are reprinted in Pet.App. F at 96a-104a (hereinafter "*Ives* V").

JURISDICTION

The judgment of the United States Court of Appeals for the Second Circuit, sought to be reviewed herein, was entered on January 8, 1981. Petitioners' subsequent timely petition for rehearing with suggestion for rehearing *en banc* was denied on February 25, 1981. This Court granted petitioners' request for an extension of time within which to file their petition for a writ of *certiorari* to and including June 25, 1981. The petition for a writ of *certiorari* in Case No. 80-2182 was duly filed on June 24, 1981, and granted on October 13, 1981. 28 U.S.C. §2101(c); Supreme Court Rules, 20.2, 20.4, 20.6 (1981). By order of the Court, the petition was consolidated with Petition No. 81-12 filed on behalf of Darby, Sherry, Rugby and MD. *See* 50 U.S.L.W. 3278 (October 13, 1981).

The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The constitutional provisions involved herein are Article I, §8, clause 8 of the Constitution of the United States and the First Amendment to the Constitution of the United States. The

federal statutory provisions involved herein are §§32 and 43(a) of the Lanham Act [15 U.S.C. §§1114; 1125(a)]. The state statutory provisions involved herein are N.Y. Education Law §§6810; 6815(2)(h), (j); 6816; 6816-a (McKinney's Supp. 1981); and N.Y. Public Health Law §206(l)(o) (McKinney's Supp. 1981).

Due to the length of these provisions, they are all reprinted in full in Pet.App. G at 106a-122a.

STATEMENT OF THE CASE

Introduction

This proceeding arises from the opinion of the United States Court of Appeals for the Second Circuit in *Ives* IV, directing the issuance of an injunction against petitioner Inwood and the other petitioners herein [*Ives* IV at Pet.App. 83a, 86a]. The court held that petitioners could not continue to market a drug product identified generically as "cyclandelate" in capsules which are colored either blue or blue/red in 200 and 400-mg. dosages, respectively.

Respondent Ives Laboratories, Inc. ("Ives") markets a cyclandelate drug product under the brand name "CYCLOSPASMOL". Ives claims in this action that, with respect to cyclandelate, it has the exclusive right to these otherwise common capsule colors.

After the Second Circuit had affirmed a denial of Ives' motion for a preliminary injunction, a bench trial was held in the United States District Court for the Eastern District of New York (Nickerson, J.). The trial court rejected all of Ives' numerous factual and legal theories. On the second appeal, however, the Court of Appeals reversed. The reversal was based solely upon what throughout the proceedings had been considered the least significant of all of Ives' claims for relief — that petitioners were liable for "contributory trademark infringement".[1] *See Ives* IV at Pet.App. 86a, n.1 (Mulligan, J., dissenting). It is therefore necessary to review the facts and course of proceedings below in some detail.

1. Ives' complaint mentioned "contributory trademark infringement" only tangentially in the midst of alleging a common-law unfair competition claim (Cont'd)

Parties Hereto and the Nature of their Business

Ives is a pharmaceutical company which manufactures and sells, among other items, a drug product in interstate commerce under the aforementioned brand name "CYCLOSPASMOL". The active ingredient in the CYCLOSPASMOL product is generically identified as cyclandelate.[2] CYCLOSPASMOL is a registered trademark owned by Ives [Pre-trial Order ("PTO"), Stipulated Fact #10, J.A. 34a].

In the trade, Ives is known as a brand-name pharmaceutical house. It heavily promotes and advertises the sale of brand-name drugs, such as CYCLOSPASMOL [Tr. 27a-30a, J.A. 86a-89a].[3] *See also Ives* III at Pet.App. 57a. The focus of its nationwide promotional efforts is to popularize its brand name for a given drug product. These promotional efforts are directed only to physicians, pharmacists and other health professionals [Tr. 64a, J.A. 97a; Tr. 67a, J.A. 98a].[4] Ives employs a nationwide sales force which "details" its brand-name drugs by making personal visits to doctors' offices [Tr. 8B-10B, J.A. 107a-108a]. Doctors are thereby encouraged to recommend and prescribe Ives' brand-

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(Complaint, Count II, ¶37, J.A. 21a). "J.A." references are to the Joint Appendix. All J.A. references which refer to the trial record are preceded by a "Tr." page reference indicating where the citation appears in the full record. All J.A. references which refer to exhibits are preceded by an "Ex." and "Tr." page reference in accordance with the form required by Supreme Court Rule 34.3. Other documents in the Record are identified by their docket sheet designation. In accordance with Supreme Court Rule 30.2, some record references are not included in the Joint Appendix.

2. Cyclandelate is a contraction of the chemical name 3,5,5 trimethylcyclohexyl mandelate [*See* Pl.Ex. 7, 8; Tr. 35a, 48a, J.A. 570a-571a]. *See, generally, Abbott Laboratories v. Celebrezze*, 228 F.Supp. 855, 863 (D.Del. 1964), *vacated on other grounds*, 352 F.2d 286 (3d Cir. 1965).

3. It has been estimated that the advertising expenditures of the large drug manufacturers to physicians amount to approximately 24% of every sales dollar. *See* Willig, *The Prosubstitution Trend in Modern Pharmacy Law*, 6 U.MICH.J.L. REFORM 1, 16 (1972). The cost of this advertising is, "of course, reflected in the increased cost of their drugs." *See* Note, *Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws*, 67 KY.L.J. 384, 390 (1978-79) (hereinafter *Consumer Protection*)

4. Drug companies may not advertise prescription drugs to the public. *See, e.g.*, 21 C.F.R. §200.7 (1981).

name drugs to the exclusion of available alternatives. *Ives* II at Pet.App. 31a.[5]

Petitioner Inwood is known in the pharmaceutical trade as a "generic drug manufacturer."[6] This branch of the pharmaceutical industry does not engage in substantial nationwide advertising or promotion through a nationwide sales force [Tr. 657, J.A. 225a; Pl.Ex. 143 at 7, 10, Tr. 109B, 947, J.A. 385a]. Inwood, for example, has three outside agents who call on wholesalers, distributors, large chain stores and hospitals to solicit orders for its drug products [Pl.Ex. 144 at 9-10, Tr. 109B, Tr. 947, J.A. 409a]. These products are not promoted by brand name, but rather are labeled and sold under their generic designation [Tr. 655-656, J.A. 223a-224a; Pl.Ex. 48-60, Tr. 107B-108B, J.A. 586a-652a]. Inwood also solicits its accounts by mailing price sheets which list its available drugs [Pl.Ex. 49, Tr. 107B, 108B, J.A. 609a-618a]. Inwood, like most generic drug manufacturers (including Premo), does not for the most part sell directly to or solicit orders from individual retail pharmacies.[7] The key factor in Inwood's ability to compete with brand-name houses such as Ives is the extent to which generic drugs are accepted in the marketplace on their own merit, rather than on fanciful advertising and promotion. Inwood and other generic drug manufacturers compete against each other in selling generic drug products to distributors and wholesalers [PTO, Stipulated Facts 27-30, J.A. 37a]. Many of the same distributors and wholesalers also purchase drug products from the brand-name companies. Petitioners Darby and Sherry, for example, thus offer both the brand-name product and the generic product to the individual retail pharmacy[8] [Pl.Ex. 50-56, 58-59; J.A. 619a-643a, 647a-651a].

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5. Ives' manner of conducting business is typical of the brand-name drug industry. *Cf., United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1118, 1126 (D.N.J. 1976).

6. Petitioners Premo and MD are also manufacturers. The remaining three petitioners, Darby, Rugby and Sherry, are distributers of generic drug products.

7. As noted by Judge Nickerson, Inwood does sell to some retail accounts [*Ives* III at Pet.App.37a]. These accounts are primarily chain stores, which function as a distributor for a large number of their own individual pharmacies [Pl.Ex.144 at 9-10, J.A. 409a (where no Tr. reference follows an exhibit citation it indicates that such reference has previously been provided)]. *See also A.H. Robins Co. v. Medicine Chest Corp.*, 206 U.S.P.Q. 1015, 1018 (E.D.Mo. 1980) (Finding of Fact #26, noting "Inwood only sells to pharmaceutical distributors.").

8. Petitioner Rugby sells only generic drug products [Pl.Ex. 145 at 23, Tr. 109B, 948, J.A. 425a].

Certain competitive realities in the marketing of brand-name and generic drugs are undisputed.[9] Inwood and other generic companies sell their products for far less than do brand-name companies [Tr. 657, J.A. 225a; Tr. 972-973, J.A. 312a]. *See generally*, Inwood Ex. 6, [Tr. 950, J.A. 795a], Report of New York State Assembly Office of Legislative Oversight and Analysis, *Are Generics Safe?* (June 23, 1978). It is also undisputed that consumers realize savings from the purchase of generic drugs; in fact generic competition after brand-name patent expiration drastically reduces the previous monopoly price structure set during the patent life of a brand-name drug.[10]

Another central fact is that the generic names of pharmaceutical products are generally unfamiliar to the consuming public, and that even pharmacists and physicians are often hard-pressed to identify the generic names of popular pharmaceutical products [Tr. 589-590, J.A. 213a-214a; Tr. 656-657, J.A. 225a; Tr. 816, J.A. 271a; Premo Ex. 63 at 58-59, Tr. 761-762, J.A. 461a]. *See* Note, *Pharmaceutical Trademarks*, 15 TULSA L.J. 327, 342 (1979). Generic drug products are therefore typically identified as equivalents or comparable versions of the well-known brand-name pharmaceuticals [Pl.Ex. 48-60, J.A. 586a-652a]. Finally, it is undisputed that for at least 26 years,[11] it has been the general, if not universal, practice to market generic drug products in the same color as their brand-name counterparts.[12]

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9. For a comprehensive analysis of generic/brand-name drug competition, *see* DRUG PRODUCT SELECTION, STAFF REPORT TO THE FEDERAL TRADE COMMISSION (Bureau of Consumer Protection, Jan. 1979) (hereinafter "FTC STAFF REPORT"). *See also Competition in the Drug Industry:* Hearing Before the Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce (97th Cong., 1st Sess., Mar. 10, 1981).

10. *See Competitive Problems in the Drug Industry:* Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business, at 10,268 (93d Cong., 2d Sess. 1974). *See also* FTC STAFF REPORT at 41.

11. *See also* (for an early example of this practice in the context of a non-prescription product) *Heide v. Wallace & Co.*, 129 F. 649 (D.N.J. 1904), *aff'd*, 135 F. 346 (3d Cir. 1905).

12. Ives' witness, the President of the New York State Pharmaceutical Society, stated that such has been the general practice during his entire 24 years of experience as a pharmacist [Tr. 327, J.A. 176a]. Similar testimony was given by petitioners' witnesses [Tr. 770, J.A. 263a-264a; Pl.Ex. 144 at 22, J.A. 411a;

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The Impact of Drug Substitution Laws

Unlike most other commodities where trademark or unfair competition issues arise, the ultimate user of the prescription drug plays virtually no controlling role in selecting the product to be purchased: the choice of drug is made by the physician. Ives and other brand-name companies therefore seek to induce physicians to prescribe their product by engaging in extensive brand-name promotion [Tr. 27a-30a, J.A. 85a-88a; Tr. 85a-89a, J.A. 100a-103a]. Central to this marketing strategy is the fact that in all states the law permits physicians to write prescriptions by brand-name. Some 90% of all prescriptions are so written. *See* R.Bond and D.Lean, SALES, PROMOTION AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS, 85, 89 (1977).

At least until the late 1970's, most state laws required that a written prescription for a brand-name product be filled only by dispensing the identified brand. These laws, known as "antisubstitution laws", reached their highwater mark by 1972, when 47 states had laws making it illegal to substitute even chemically equivalent drugs for the particular brand named in the prescription. *Consumer Protection*, 67 KY.L.J. at 389-390. Given this setting, and in light of extensive brand-name promotion, brand-name prescribing has become, and continues to be, the predominant way in which prescription drugs are identified.

Particularly in the case of patented drugs, promotion during the life of the patent virtually obscures the generic chemical name for most prescription pharmaceuticals. Upon patent expiration, the smaller generic competitors are thereby faced with the formidable obstacle of attempting to market a product known to and prescribed by physicians primarily under the former patentholder's brand name. Under the former law of almost all states, the ingrained practice of brand-name prescribing acted as a virtual bar to effective competition, except for the limited number of instances where physicians prescribed

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Pl.Ex. 145 at 52, J.A. 431a]. At the hearing on the preliminary injunction, the undisputed evidence was that this practice has been prevalant for at least 40 years [Affidavit of Seymour Blackman in opposition to plaintiff's motion for a preliminary injunction, sworn to May 11, 1978 at ¶14].

generically[13] [Tr. 765, J.A. 262a-263a]. *See also Consumer Protection,* 67 KY.L.J. at 390.

In the mid-1970's, various states began enacting what are commonly known as "drug substitution" statutes. Recognizing that physicians prescribe by brand name, even after patent expiration, due to a lack of familiarity with the generic name, these statutes specify circumstances under which the pharmacist may, and in some states must, dispense a lower-cost generic drug product, even if the physician has identified a brand name on his written prescription. *See, e.g.,* N.Y. EDUC. LAW §§6810; 6815(2)(h), (j); 6816; and 6816-a (Pet.App. at 112a-122a).[14] These statutes do not prohibit brand-name prescribing. Rather, they recognize that the physician's utilization of a brand-name identification may simply be a shorthand description of the active ingredient, without the exercise of any medical judgment or preference that solely the brand-name product be utilized.

The enactment of drug substitution laws by 49 states, the District of Columbia and Puerto Rico, was accomplished despite

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13. "It is understandable that physicians do and will continue to prescribe by brand name . . . It's easier and quicker. Most drug products have three names. Take Librium. It has a chemical name intelligible only to accomplished organic chemists, not pronouncable here; a generic name— chlordiazepoxide hydrochloride; and then a tradename which, if registered, can be used exclusively. What busy physician wouldn't prefer a tradename such as Librium to the generic." *FDA Drug List: Key to Generic Substitution,* FDA CONSUMER (Feb. 1979) at 17. [*See also* Tr. 589-590, J.A. 213a]

14. For a comprehensive analysis of the drug substitution laws, *see Consumer Protection,* 67 KY.L.J. at 395-407. For an updated compilation, *see* National Association of Board of Pharmacy Survey of Pharmacy Law (1981-82) at 27-28. The format for these statutes varies from state to state. In many, the law is permissive in nature, *i.e.,* the pharmacist is permitted, usually with the patient's consent, to dispense a less-expensive generic product. In some states, as in the case of New York, generic dispensing is mandatory if the product in question and its generic manufacturer are listed in an approved state formulary. Most states require that written prescriptions be on a form which contains two lines for the physician's signature. The physician indicates whether substitution is permissible or impermissible by signing his name on the appropriate line. (In New York, otherwise mandatory substitution becomes "permissible" if the product is not listed in the official formulary. *See Ives* IV at Pet.App. 77a, n.5). In other states, generic dispensing is automatically authorized unless the physician indicates to the contrary by affirmatively writing on the prescription such terms as "dispense as written" or "no substitution."

the vigorous opposition of the brand-name companies.[15] The impact of the generic substitution laws on the more than 8 billion dollar prescription drug market is therefore clear.[16] After a patent expires, brand-name drug companies can no longer rely on the fact that prescribing physicians are unfamiliar with the generic names of the drug products which they prescribe. They must instead seek to persuade the prescriber to affirmatively insist on the brand name by indicating on the prescription forms that substitution is impermissible, or that the prescription should be dispensed as written. *Ives* II at Pet.App. 31a.

The Course of Proceedings Below

Cyclandelate, a prescription drug product, has been marketed as a vasodilator for use in the treatment and management of peripheral and cerebral vascular diseases[17] [PTO, Stipulated Fact #19, J.A. 36a]. It is not used to cure any disease; rather its action is for the purpose of inhibiting the otherwise progressive and debilitating effects of the indicated conditions, which generally occur in the elderly [Tr. 43a, J.A. 94a; Tr. 859, J.A. 286a]. Once prescribed, and assuming the physician is satisfied with the therapeutic effect, the use of this drug necessarily becomes long-term and continues for the duration of the patient's lifetime [PTO, Stipulated Fact #19, J.A. 36a]. By reason of the nature of their conditions, patients taking cyclandelate are often disoriented and subject to emotional fears and stress [Tr. 859, J.A. 286a].

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15. *See* Haddad, *Generic Drugs — Tomorrow's Market*, 33 FOOD, DRUG & COSM.L.J. 488, 489 (1978). *See also Pharmaceutical Mfrs. Ass'n v. Kennedy*, 471 F.Supp. 1224 (D.Md. 1979); *Pharmaceutical Society of New York, Inc. v. Lefkowitz*, 586 F.2d 953 (2d Cir. 1978); *Pharmaceutical Mfrs. Ass'n v. Whelan*, ___ Misc.2d ___, Index No. 15831/78 (Sup.Ct.N.Y.Co., Aug. 15, 1980), *aff'd without opinion*, 79 A.D.2d 876, 435 N.Y.S.2d 618 (1st Dept., Dec. 4, 1980), *appeal pending* (attacking generic substitution law as unconstitutional, promoting trademark infringement and unfair competition, and depriving brand-name companies of due process).

16. *See generally*, FTC STAFF REPORT at 25-28. *See also* SRI International, *Pharmaceutical Industry Perspectives: A U.S. Generics Breakthrough?* (May 1980).

17. Its rationale for use under these conditions is that upon ingestion there is an increase in the blood flow of otherwise-constricted peripheral blood vessels. It is indicated as adjunctive therapy in such conditions as intermittent claudication, arteriosclerosis obliterans, thrombophlebitis (to control associated vasospasm and muscular ischemia), nocturnal leg cramps, Reynaud's phenomenon, and for selected cases of ischemic cerebral vascular disease [Pl.Ex. 11, Tr. 29a-31a].

Since 1958, Ives has sold cyclandelate as a heavily promoted brand-name product known as "CYCLOSPASMOL". By 1962, Ives was marketing two CYCLOSPASMOL dosage forms; an orange, 100-mg. tablet,[18] and a blue, 200-mg. capsule. Until April 26, 1972, Ives was immune from competition in the United States for its cyclandelate product by virtue of a patent which had been issued to its predecessor-in-interest [*Ives* II at Pet.App. 31a]. In 1975, Ives began marketing a 400-mg. dosage form of cyclandelate in a blue/red capsule. Blue and blue/red capsules as such are not unique or distinctive in the pharmaceutical trade [*See, e.g.*, Tr. 596, J.A. 218a; Pl.Ex. 137, Tr. 939 — *Physician's Desk Reference*, Product Identification Section at 434 for E.R. Squibb's VELOSEF product]. Ives has never applied for registration of either color configuration as a trademark, copyright or design patent. Ives imprints its name and an accompanying identifying number of both the 200-mg. and 400-mg. dosage forms.

Despite its long history of use, the efficacy of cyclandelate for its intended purposes remains in doubt. As part of the historic DESI review conducted by the FDA,[19] cyclandelate was found lacking in efficacy for some of its indications and only possibly effective for others [Pl.Ex. 11, Tr. 29a, 48a]. FDA has since proposed that cyclandelate be withdrawn from the market, and that Ives' prior approval to market CYCLOSPASMOL be revoked. 44 F.R. 30436-37; 30443-46 (May 25, 1979) [Inwood Ex.7, Tr. 950; *see also* Tr. 92B, J.A. 122a-123a]

The foregoing is relevant in two respects. First, efficacy questions have prevented the listing of cyclandelate in certain state formularies, with the result that substitution in such states as New York is permissive, rather than mandatory. *See Ives* IV at Pet.App. 77a, n.5. Second, the possible lack of efficacy raises the distinct possibility that the primary, if not entire, effect of cyclandelate is due to its function as a placebo. For an example of a widely prescribed drug being classified as a placebo, *see Mead Johnson & Co. v. Premo Pharmaceutical Laboratories, Inc.*, 207 U.S.P.Q. 820, 826 (D.N.J. 1980) [finding of fact #136]. It is undisputed that the placebo effect can play an important role, even for medications which are considered

18. The tablet is not at issue in this litigation.

19. *See Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 614-615 (1973).

therapeutically effective. [*See* Tr. 57B, J.A. 118a-119a; Tr. 414-415, J.A. 195a-196a]

In 1976, Inwood commenced manufacturing and marketing a generic cyclandelate product to compete with CYCLOSPASMOL [Pl.Ex. 144 at 20, J.A. 410a]. Inwood marketed its cyclandelate product to its wholesaler and distributor accounts in exactly the same way that it and other generic companies have marketed their products for the last 40 years. Inwood sold its 200-mg. dosage form in a blue capsule and its 400-mg. dosage form in a blue/red capsule, *viz.*, the same colors previously used by Ives. As with other products, Inwood's cyclandelate was listed on the price sheets it distributed [Pl.Ex. 49, J.A. 609a]. These sheets merely identified the generic name, color and price of Inwood's product. A separate column identified the brand-name product to which each generic product corresponded.[20]

At trial, Ives' witnesses admitted that it had known of the competitive marketing by Inwood from its very inception [Tr. 69a, J.A. 98a-99a]. This lawsuit, however, was not commenced until more than two years later—Feb. 28, 1978.[21] By this time, the nationwide sweep of the movement towards "drug substitution" was almost complete. Also underway was a widespread effort by brand-name manufacturers, seeking to reverse the historical trend by which generic drug products were marketed in colors similar to the brand-name products.[22]

Thus, on the eve of the effective date of the New York substitution law (April 1, 1978), Ives commenced the instant case against the petitioners. One individual retail pharmacy located in New York State was also included as a defendant. Ives alleged, *inter alia*, that this pharmacy (Lowitt Labs, Inc.) had filled two

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20. This innocuous document [Pl.Ex. 49] ultimately became the key factor in the finding that Inwood was liable as a contributory trademark infringer. A replication of this document is set forth in the Joint Appendix [J.A. 609a-618a].

21. Ives asserted that it had only "gradually" become aware of the injury supposedly being caused by the sale of generic cyclandelate products [Tr. 69a, J.A. 99a].

22. The first of these appears to have been *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977), *aff'd on procedural grounds*, 579 F.2d 786 (3d Cir. 1978). The instant case is the first of a series of essentially contemporaneous lawsuits against generic companies to reach this Court. *See* discussion at Point II, *Infra*.

prescriptions for CYCLOSPASMOL by dispensing a generic version thereof [Complaint ¶47-52, J.A. 23a-24a]. The pharmacy and Ives promptly entered into a consent decree under which the pharmacy admitted having committed the acts complained of, and consented to an injunction against any unlawful substitution [J.A. 29a].

Ives also alleged: (a) one trademark infringement count against petitioner Sherry;[23] (b) an unfair competition count claiming that petitioners' use of similar capsule colors violated Ives' proprietary rights; (c) a claim under §43(a) of the Lanham Act [15 U.S.C. §1125(a)] that petitioners had engaged in false advertising by claiming their generic cyclandelate products as equivalents of Ives' CYCLOSPASMOL;[24] and (d) that petitioners' actions violated §368-d of the New York State General Business Law.

Ives moved for a preliminary injunction primarily on the grounds that the use of identical capsule colors constituted a *per se* violation of both §43(a) of the Lanham Act, and the New York State law of unfair competition. Ives further claimed that petitioners were liable for "contributory trademark infringement." Relying upon *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc., supra,* Ives contended that mere copying of capsule colors was enough to establish "secondary meaning" and its exclusive right to blue and blue/red colors.

The District Court denied the motion (*Ives* I), and the Second Circuit affirmed (*Ives* II). The Second Circuit rejected Ives' claim that secondary meaning could be established by showing merely that the capsule colors in question had been copies (*Ives* II at Pet.App. 50a-51a). It held that Ives would have to establish that consumers had come to associate the capsule colors as indicating a particular source of origin. Further, referring to the evidence of functionality described by Judge Nickerson in *Ives* I at Pet.App. 22a-24a, the Court of Appeals

23. The complaint's only reference to statutory trademark infringement is not at issue here. Sherry had discontinued the name "SPASMOL" for its cyclandelate. *Ives* I at Pet.App. 7a.

24. This claim was not supported at trial by any evidence, *Ives* III at Pet. App. 62a, and was abandoned on appeal. *Ives* IV at Pet. App. 86a, n.1 (Mulligan, J., dissenting).

noted that such evidence, if confirmed at trial, would defeat Ives' claim under §43(a) (*Ives* II at Pet.App. 48a-51a).

In support of its motion, Ives introduced evidence consisting of 15 test-shoppings where Ives personnel presented prescriptions to one pharmacy in Mississippi, one pharmacy in Pennsylvania, two pharmacies in New York, and five pharmacies in Michigan [Pl.Ex. 95-107, Tr. 248-249, J.A. 732a-782a]. These locations were selected because Ives suspected that the pharmacists in question were "bad actors" having a proclivity towards illegal substitution [PTO, Stipulated Fact #25, J.A. 37a]. Ives claimed that its suspicions were confirmed by the results of these test-shoppings and that these pharmacies had unlawfully substituted a generic brand where the prescription had called for CYCLOSPASMOL.[25]

Judge Friendly's opinion in *Ives* II held that this sparse evidence was not enough to make the petitioners vicariously liable for the acts of the few supposedly unscrupulous pharmacists. He found that Ives had shown only that similarity of capsule colors had made it easier for a druggist, already inclined to engage in unlawful conduct, to do so. *Ives* II at Pet.App. 36a. At trial, Ives would have to show that petitioners had "suggested, even if only by implication", that pharmacists engage in conduct which infringed Ives' trademark, and that such conduct was "much more widespread" than suggested by the meager evidence introduced by Ives below. *Id.* at Pet.App. 35a, 52a-53a.

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25. Actually, the Michigan test-shoppings were not examples of "illegal substitution." Michigan had already enacted a drug substitution law. MICH. COMP. LAWS ANN. §338.1114a (Supp. 1975-76). The prescriptions in question had not specified "dispense as written," and the pharmacist, under the law, was thus entitled to dispense the generic, rather than the brand-name drug. *Id* at §338.1114a(3)(b). *See* Note, *Improving Michigan's Generic Drug Law*, 9 MICH. J.L. REFORM 394, 402 (1976). Significantly, three of the Michigan pharmacists clearly labeled the product dispensed as the equivalent product of another manufacturer of cyclandelate, *e.g.*, "Premo Equivalent" [*see* Pl.Ex. 95, 98, 102, J.A. 732a, 744a, 760a]. Although these pharmacists used the name "Cyclospasmol," it has been noted that the early Michigan statute had engendered serious confusion among pharmacists. *Id.*, Note at 400-401. *See also Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F.Supp. 413, 422 (E.D.Mich. 1979), *appeal dismissed*, 615 F.2d 1362 (6th Cir. 1980).

The "Additional Evidence" Produced By Ives

At trial, Ives did not attempt to show any further evidence of "illegal substitution" beyond that already found in *Ives* II to be insufficient to support a finding of contributory infringement.[26] Accordingly, at trial, Ives did not contend that "illegal substitution" for CYCLOSPASMOL was any more widespread than the original 15 instances which had been adduced in connection with the motion for a preliminary injunction [Tr. 85-86, J.A. 145a; Tr. 394]. In fact, Ives' own witness, the Executive Director of the New York State Pharmaceutical Society, further testified that "illegal substitution" was, in fact, not widespread [Tr. 352-353, J.A. 182a][27]. Attempting nevertheless to satisfy the Second Circuit's standard regarding contributory trademark infringement,[28] Ives conducted a survey intended to show that instances of *lawful* substitution under the New York State drug substitution law might produce instances of trademark infringement. To this end, Ives surveyed 83 pharmacies in New York State, 42 of which were selected by Ives personnel and 41 of which were selected at random from a directory of New York State pharmacies. Ives' test-shoppers presented a prescription to these pharmacists, which mentioned CYCLOSPASMOL, and was signed on the line of the New York prescription form affirmatively noting "substitution permissible" [Pl.Ex. 83, Tr. 83, 92, J.A. 354a].

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26. The evidence showed that a survey could have easily been done to reveal the extent of "illegal substitution," if any, with respect to CYCLOSPASMOL [Tr. 567-568, J.A. 205a]. Ives expressly advised the Court that it would not undertake to do so [Tr. 86, J.A. 145a; Tr. 394; *see also* Tr. 120a, J.A. 106a-107a].

27. See also *Ives* IV at Pet.App. 89a, n.2 (Mulligan, J., dissenting).

28. "The authorities later reviewed by us indicte that a manufacturer or wholesaler would be liable under §32 if he suggested even if only by implication that a retailer fill a bottle with generic capsules and apply Ives' mark to the label or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described." *Ives* II at Pet.App. 35a-36a.

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"Discovery and trial might show that the practice was much more widespread or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices." *Ives* II at Pet.App. 53a.

A total of 35 pharmacists in this limited survey[29] *lawfully* dispensed a generic product[30] [Tr. 85-86, J.A. 145a]. Of these, 10 included the word "CYCLOSPASMOL" in some fashion on the label of the dispensing container. Five of this latter group labeled the product as follows:

> "Generic Cyclospasmol" [Pl.Ex. 82-000, J.A. 691a;[31] Pl.Ex. 82S, J.A. 695a[32]].
> "Cyclospasmol Generic" [Pl.Ex. 82E, J.A. 699a; Pl.Ex. 82SSS, J.A. 703a].
> "Cyclospasmol Gen (Spencer Mead)" [Pl.Ex. 82TTT, J.A. 707a]. [All bottles which make up Exhibit 82 were offered into evidence at the same time. (Tr. 85-86, 92)]

Of the remaining five, two pharmacists appeared to have listed the name of the manufacturer, as required under New York law, *viz.*, "Cyclospasmol 400mg. (Rugby)" [Pl.Ex. 82BB, J.A. 711a][33] and "Hylan: Cyclospasmol" [Pl.Ex. 82A, J.A. 715a]. The other three [Pl.Ex. 82DDD, J.A. 726a; 82 HHH, J.A. 723a; 82T, J.A. 719a] listed only the name "Cyclospasmol". Thus, a total of seven pharmacists wrote the term "generic" either on the label or on a receipt and/or listed the name of the generic manufacturer. All of the pharmacists except one either spontaneously or in response to an inquiry expressly informed the customer that the generic product had been dispensed. For example, as indicated by Pl.Ex. 82BB, J.A. 712a, the pharmacist informed the patient orally, "[T]he generic was dispensed on account of its lower cost." *See also* Pl.Ex. 82S, J.A. 696a, where the pharmacist told

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29. As observed by Judge Mulligan, the shopping of 83 pharmacies in one state (half of which were selected by Ives under circumstances which are at best unclear) had no statistical validity, *Ives* IV at Pet.App. 87a, 89a. An expert testified that this survey was "winged casually" and contained "figures engineered with their basis to inflate them in a way that would be misleading."[Tr. 640-643, J.A. 222a-223a].

30. The balance dispensed the brand-name product because they either did not have the generic product available or erroneously believed that a generic product could not be dispensed.

31. This pharmacist also listed the name of the generic manufacturer.

32. This pharmacist applied a label stating, "[A] generic equivalent drug has been dispensed of the same quality and at a lower price."

33. In addition, this pharmacist gave the customer a receipt expressly stating that a generic had been dispensed.

the customer that CYCLOSPASMOL was three times more expensive than the generic. This was consistent with the practice of many other pharmacists in the survey who dispensed the generic and emphasized the cost-savings to customers. (*See* Pl.Ex. 82-000; 82L; 82W; 82X; 82VVV; 82XXX.) As found by Judge Nickerson, *Ives* III at Pet.App. 60a, and noted by Judge Mulligan in his dissent, *Ives* IV at Pet.App. 88a, only one pharmacist "appeared" to have charged a brand-name price.[34]

The *Ives* II opinion had directed that petitioners could be liable for contributory infringement only if they suggested to pharmacists, even by implication, that they infringe Ives' trademark, or if petitioners continued to sell to a pharmacist whom they knew were infringing the trademark. On the latter score, Ives introduced no evidence, and did not claim below that any of the petitioners continued sales to a pharmacist whom they knew or should have known was engaged in illegal substitution or mislabeling. *Ives* III at Pet.App. 59a. *See also Ives* IV at Pet.App. 87a-88a (Mulligan, J.). Instead, Ives sought to satisfy the "suggestion by implication" prong of the standard established in *Ives* II by introducing various catalogs and promotional materials disseminated by petitioners. Ives claimed that by way of these materials, petitioners "suggested by implication" that pharmacists mislabel lawfully dispensed generics as CYCLOSPASMOL.

In the case of Inwood, these "catalogs" consisted solely of price sheets listing various drug products, including cyclandelate [Pl.Ex. 49, J.A. 609a-618a]. The price sheets, under appropriate column headings, list (1) the name of the equivalent brand-name product, (2) the generic description of the product available from Inwood, (3) the strength of each drug, (4) the color of each dosage form, and (5) Inwood's price. Cyclandelate is in no way singled out by the price sheet or by any catalogs distributed by the other petitioners.

Inwood's price sheets were distributed only to its wholesaler, distributor, chain store and hospital accounts [Pl.Ex. 144 at pp. 9-10, J.A. 409a]. Ives introduced no evidence that any

34. An additional survey of 25 pharmacies showed that when lawful substitution occurred, 23 pharmacists labeled the container as cyclandelate without reference to CYCLOSPASMOL, and 2 pharmacists labeled it as "Cyclopasmol Generic" [Pl.Ex. 142, Tr. 957, J.A. 375a-382a].

retail or dispensing pharmacist had seen the price list.[35] As a matter of evidence, there was thus no possible basis for a finding that Inwood or the other two manufacturer-petitioners had actually or impliedly suggested anything to any pharmacist.[36]

Ives also introduced the catalogs of the wholesaler petitioners [Pl.Ex. 50-59, J.A. 619a-652a]. In the case of Darby, which sells both the Ives CYCLOSPASMOL brand and generic cyclandelate, one section of the catalog advertised the availability from Darby of both brand-name and generic products. Cyclandelate is one of the products listed in this section. Darby's prices for cyclandelate and Ives' CYCLOSPASMOL are listed; no reference is made to color [Pl.Ex. 50 at p. 4, J.A. 622a]. Other sections of Darby's catalog list generic and brand-name products and their prices separately [*Id.* at p. 3, J.A. 621a]. In the generic listing, products are identified as a generic for the brand-name, and the color of Darby's product is noted.[37] Although the catalogs of the wholesaler petitioners are distributed to pharmacists, it is difficult to understand how these catalogs constituted an implied suggestion to pharmacists to engage in illegal conduct.[38]

The Role of Capsule Colors for Prescription Drugs

The uncontradicted evidence below established that a change in the color of a prescription pharmaceutical plays an important role in the patient's initial reaction to the drug

35. There was no such evidence for any of the other manufacturer's price lists as well.

36. Petitioner MD's "catalog" was similarly only a product list which, moreover, did not contain any color references [Pl.Ex.60, J.A. 652a].

37. Sherry's catalog was similar, except that cyclandelate and CYCLOSPASMOL were not listed side by side, but rather separately at their respective alphabetic positions [Pl.Ex. 51 at pp.2-3, J.A. 624a-625a]. As already noted, Rugby sells only generic drugs. Its catalog includes a chart identifying which of its generic products correspond to the national brand and a separate section where the price of the generic product (but not CYCLOSPASMOL) is listed [Pl.Ex. 57 at p.3, J.A. 646a].

38. Since Judge Mansfield's discussion does not accurately describe any of the catalogs, we respectfully ask this Court to examine these catalogs in order to assess what significance, if any, they have on the issue of contributory trademark infringement.

product after it is dispensed. Some of the strongest evidence in this respect came from Ives. In its unsuccessful attempt to prove that the blue and blue/red capsule colors have a secondary meaning, Ives established that for patients taking CYCLOSPASMOL, the color of the product is central to the patient's identification of their medication.[39] The Ives survey on secondary meaning, for all its deficiencies,[40] showed that 79% of patients surveyed identified the capsules presented to them by their color alone [Pl.Ex. 74 at 7, Tr. 70-72, 92, J.A. 332a]. No one disputed the result of an unexplained change in capsule color: it was agreed that virtually all patients would believe that a mistake had been made in filling their prescription in the absence of a prior explanation by the pharmacist or dispensing physician [Tr. 62a-63a, J.A. 96a; Tr. 37B, J.A. 111a; Tr. 51B, J.A. 116a; Tr. 311, J.A. 172a; Tr. 316, J.A. 173a; Tr. 353, J.A. 182a-183a; Tr. 577, J.A. 206a; Tr. 582, J.A. 210a-211a; Tr. 667-668, J.A. 230a; Tr. 687, J.A. 233a-234a; Tr. 691, J.A. 236a; Tr.

39. As the Vice President of Ives stated in his affidavit in support of Ives' motion for a preliminary injunction at ¶18:

> "[T]he patient receiving his prescription for CYCLOSPASMOL cyclandelate capsules relies on their distinctive appearance to assure himself that they are the same capsules which he has previously taken. In the case of CYCLOSPASMOL, the patient rapidly becomes familiar with the distinctive color of Ives' cyclandelate capsules because . . . the treatment and management of peripheral vasodilator disorders takes place over an extended time period, requiring at least months and in some cases years of continuous treatment. In fact, practically 100% of the patients on cyclandelate treatment are repeat users. Therefore, patients taking Ives' CYCLOSPASMOL cyclandelate are continuously and for extended time periods exposed to the color of the 200 mg. and 400 mg. CYCLOSPASMOL capsules. This extended exposure leaves the patient with a strong visual picture of the appearance of the product he is taking and he relies upon the appearance of the product as assurance that he is always receiving the same identical product that his physician prescribed." *See* Affidavit of Herbert Lowenkron, sworn to March 2, 1978.

Mr. Lowenkron confirmed his affidavit statements at trial [Tr. 62a-63a, J.A. 96a].

40. The survey was plagued with significant difficulties of execution. Statistical projectibility was completely compromised by the fact that only a 20% response rate at the initial level could be obtained [Tr. 610-613]. *See generally*, 1-Part 2 MOORE'S FEDERAL PRACTICE at 123-157 (2d Ed. 1979).

708-709, J.A. 246a; Tr. 734-735, J.A. 249a; Tr. 748, J.A. 257a; Tr. 775, J.A. 265a; Tr. 868-872, J.A. 291a-294a].

Further, many patients associate the appearance of a medication with its therapeutic effect[41] [Tr. 578, J.A. 207a; Tr. 684, J.A. 231a; Tr. 774, J.A. 264a; Tr. 865, J.A. 289a; Tr. 878, J.A. 299a]. Some patients accept a pharmacist's explanation that a color difference results merely from a change in brand. Many, however, refuse to accept their pharmacist's explanation and insist on contacting their physician [Tr. 690-691, J.A. 236a; Tr. 735-736, J.A. 250a; Tr. 975, J.A. 313a]. Thus, some patients may eventually accept changes in color, but only after having experienced considerable anxiety and confusion. *Ives* III at Pet.App. 63a. Finally, there was extensive testimony that some patients refuse to accept equivalent drugs, even after all explanation, solely because of differences in color [Tr. 581-583, J.A. 209a-211a; Tr. 695, J.A. 238a; Tr. 735-736, J.A. 250a; Tr. 826-827, J.A. 277a].

The problem of anxiety and confusion is particularly important in the case of a maintenance drug such as cyclandelate, where the patient, by reason of his or her long period of use, becomes strongly accustomed to a single appearance [Tr. 579, J.A. 208a; Tr. 698-699, J.A. 240a; Tr. 734, J.A. 249a; Tr. 869, J.A. 292a-293a]. There was testimony that on occasion doctors insist on a specific brand for institutionalized patients solely because they wish to avoid an anxiety producing color change [Tr. 828-829, J.A. 278a]. Elderly patients are particularly apprehensive, and even frightened, by changes in color of their medication [Tr. 582, J.A. 206a; Tr. 695, J.A. 238a; Tr. 734, J.A. 249a; Tr. 870-871, J.A. 292a-293a].

Uniformity of color was considered critical in institutional settings where a central pharmacy must dispense medications to numerous patients without the benefit of immediate container labeling at the point where each patient receives the product [Tr. 823-826, J.A. 274a-277a]. It was shown that one manufacturer who attempted to sell cyclandelate in a color different from that marketed by Ives was forced to discontinue the product within a

41. Such descriptions as "my red heart pill" or "blue stroke pill" are common [Tr. 578, J.A. 207a; Tr. 734, J.A. 249a; Tr. 865, J.A. 289a. *cf.*, Tr. 488, J.A. 116a; Tr. 318, J.A. 173].

year after its introduction when its hospital clientele refused to accept it precisely because of the color difference [Tr. 830-831, J.A. 279a-281a; Pl.Ex. 144 at 28-29, 66-68, J.A. 412a, 417a-418a]. The Chief Pharmacist of one such hospital testified that, in making decisions on which generic products to purchase, he first tried to ascertain whether the generic is available in the same color as its brand-name counterpart [Tr. 835, J.A. 282a].[42]

The significance of color also extends beyond the point where the product is first dispensed. Patients taking multiple medications, as do many elderly, frequently comingle various drugs in a single container.[43] These patients rely on color to identify the time and frequency for taking their medications [Tr. 54B, J.A. 118a; Tr. 739, J.A. 253a; Tr. 864-865, J.A. 288a-289a]. Even without comingling, physicians in instructing their patients on occasion specify regimens with specific reference to color [Tr. 737-738, J.A. 251a-252a; Tr. 870, J.A. 292a]. *See also Ives* III at Pet.App. 63a.

Changes in color among different brands for the same product are thus a certain source of confusion, anxiety and potential danger for these patients [Tr. 576, J.A. 206a; Tr. 862, J.A. 288a]. Moreover, in emergency situations, where every possible clue must be used in quickly determining or at least estimating which drug an overdose victim has ingested, color, to the extent feasible, was shown to be a valuable aid [Tr. 583-584, J.A. 211a-212a; Tr. 695-696, J.A. 238a-239a, Tr. 742, J.A. 254a; Tr. 874-877, J.A. 296a-298a]. *See also Ives* III at Pet.App. 63a.

Colors serve to identify different dosage strengths of the same therapeutic entity. Ives uses different colors to identify the 200-mg. and 400-mg. dosages, respectively. Ives admitted that for this, as well as its other drug products, color performs this valuable identification function [Tr. 21a, J.A. 83a; Tr. 52a, J.A.

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42. Although it is no longer a general practice, at least one state (New Jersey) required all bidders for cyclandelate procurement contracts to offer the product in blue and blue/red colors [Inwood Ex.11, Tr. 978-980, 986, J.A. 833a].

43. There is extensive testimony that this is done despite the recommendation of doctors that it is not a desirable practice [Tr. 53B-54B, J.A. 117a-118a; Tr. 319, J.A. 174a; Tr. 576-580, J.A. 205a-209a; Tr. 685, J.A. 231a-232a; Tr. 739, J.A. 252a; Tr. 864, J.A. 289a; Tr. 865, J.A. 290a].

95a-96a; *see also* Tr. 832-833, J.A. 281a-282a; Tr. 883, J.A. 301a].[44]

As noted previously the placebo effect for a drug which, like CYCLOSPASMOL, may be of only marginal effectiveness, is of great significance. One of Ives' principal witnesses acknowledged that the placebo effect is often even stronger than the actual pharmacological effect [Tr. 415a, J.A. 195a]. It is undisputed that changes in color can significantly alter the placebo effect for a given patient [Tr. 57B, J.A. 118a-119a; Tr. 414-415, J.A. 195a].[45] The scientific literature shows that specific color configurations are directly related to psychological efficacy of a given drug product *i.e.*, green being preferred for anxiety, yellow for depression, etc.[46]

The District Court's finding of functionality of the capsule colors was therefore firmly rooted in the evidence.[47] If generic

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44. At the hearing on a preliminary injunction, it was shown that one company prominently advertised its various dosage strengths: "No other antidepressant offers SIX TABLET STRENGTHS EACH WITH ITS OWN COLOR. . . . An important feature: The six tablet strengths which makes ELAVIL (Amitryptaline HCL, MSD) so versatile are color coded to facilitate identification and help accurate dispensing." *See* Ex.3 to the Affidavit of Seymour Field in opposition to plaintiff's motion for preliminary injunction, sworn to May 11, 1978. *But cf.*, Judge Biunno's varying, if not novel, discussion of the same evidence in *Biocraft Laboratories, Inc. v. Merck & Co., Inc.*, ___ F.Supp. ___, Civ. Action No. 77-693 at 17-18 (D.N.J. Oct. 2, 1980).

45. This Court has taken note of the well-established fact that identity of appearance is an essential aspect of the placebo effect. *See Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. at 635 (Appendix). *See also Warner-Lambert Co. v. FTC*, 562 F.2d 749, 754, n.9 (D.C.Cir. 1977), *cert. denied*, 435 U.S. 750 (1978).

46. *See, generally*, Schapira, et al., *Study on the Effects of Tablet Colour in the Treatment of Anxiety States* (1970) BRIT. MED J. 2:446-449; A. Leslie, *Ethics and Practice of Placebo Therapy*, 16 AM.J.MED. 854, 859 (1954); D.S. Trouton, *Placebos and Their Pschycological Effect*, 103 J.MENTAL SCI. 344 (1957); S. Dichter, *Handbook of Consumer Motivations*, 228 (1964); C.W. Gowdy, J.T. Hamilton and R.B. Philip, *A Controlled Clinical Trial Using Placebos in Normal Subjects: A Teaching Exercise*, 96 CAN.MED. ASS'N J. 1317, 1320 (1967). *See also Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F.2d 569, 572 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960); 3 R. Callman, UNFAIR COMPETITION §82.1(m) at 196 (Supp. 1980). (hereinafter "CALLMAN")

47. Significantly, courts outside the United States have recently made findings virtually identical to those of the District Court. *See Boots Co. Ltd.*

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companies are required to introduce their product in a color different from that of the brand-name company, it will, in the hands of the ultimate consumer, be regarded in the first instance as a mistake [Tr. 699, J.A. 240a]. The generic company's product is therefore placed at the discretion of pharmacists and physicians in terms of their ability to effectively convince patients that the color differences should not affect therapeutic efficacy. A requirement for use of a different color on an equivalent drug thereby places a burden on the marketing of the generic company's product which is not present in the case of the brand-name product. The end result is that color, because of its special role in the eyes of the patient, becomes a factor in the decision of the patient to take a product, the decision of the physician to prescribe a product, and the decision of institutions such as hospitals to purchase the product.[48]

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v. Approved Prescription Services, Ltd., [1980] ___ Ch. ___, B.No. 140 (Unreported: Martin Meredith) (Ch. Div'l. Ct. March 6, 1980), *aff'd*, [1980] B. No. 140 (Unreported: Association) (Court of Appeal Civ. Div. March 28, 1980):

> "There is a good deal of evidence which shows that in connection with other drugs different manufacturers do use exactly the same shape and colour or shapes and colours which are, to a fair approximation, the same; and the reason why they do so is because apparently, if patients have been used in treatment to a pill or capsule of a particular shape and colour, even if the pill they are then offered is a pill containing exactly the same ingredients in a similar formulation, they are not prepared to accept it if the size, shape and colour are different, this being in a sense a purely psychological blockage as far as the patient is concerned."

See also Roche Products Ltd v. Berk Pharmaceuticals, Ltd., [1973] RPC 473 (Supreme Court of Judicature).

48. It should be noted that part of the opposition to enactment of drug substitution laws was based in part on contentions that patients would be subject to anxiety and stress as a result of potential changes in color:

> "Also, as there is always a certain amount of apprehension about taking medications, even those prescribed by a trusted physician, imagine the problems that would be created when the blood pressure pills are one month pink and the next month white and when those that were round one month are the next month rectangular, square or octagonal. The anxiety produced by repeated exposure to unfamiliar size, shape, and color would be sufficient to cause some people to discontinue their treatment program either in whole or in part. I need not detail the damage and even deaths that would result as a consequence of this particular problem." Testimony of

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As pointed out in Department of Health and Human Services, GUIDE TO PRESCRIPTION DRUG COSTS; HCFA-02104 (April, 1980):

> "The FDA proposes to consider products as therapeutically equivalent if they meet the policies outlined in this document, even though they may differ in certain other characteristics, e.g., color, flavor, packaging, expiration date and minor aspects of labeling. When such differences are important in the care of a particular patient, it is appropriate for the prescribing physician to require that a particular brand be dispensed as a medical necessity." *Id.* at 159.

It may be fairly said, as Judge Nickerson found, that identity of color is an important ingredient in the commercial success of the marketing of generic drug products. *See Ives* III. *See also Pagliero v. Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1952), *accord, Ives* II at Pet. App. 49a-50a.

The Ruling of the District Court After Trial

The District Court rejected Ives' principal claim under §43(a) of the Lanham Act. It held that the functionality of capsule colors for pharmaceutical products precluded the monopoly which Ives was seeking to establish, and that in any event Ives failed to show that its capsule colors had developed secondary meaning of a single, albeit anonymous, source to the patients who received the medication.[49] In fact, the court found

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> Lawrence A. Tilis, M.D., *Prescription Drug Labeling and Price Advertising*, Hearings Before the Subcomm. on Consumer Protection and Finance for the House Comm. on Interstate and Foreign Commerce at 176 (94th Cong., 2nd Sess. April 22, 1976).

49. In fact, it was almost impossible for Ives to demonstrate secondary meaning as of the late date it conducted its survey, *see Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F.Supp. 762, 769 (E.D.Mich. 1972), *aff'd without opinion*, 473 F.2d 910 (6th Cir. 1973). By that time, approximately 22 companies were manufacturing and/or distributing cyclandelate in the same colors as those used by Ives [*See* Inwood Ex.12, Tr. 955, J.A. 444a, and *Ives Laboratories, Inc. v. Bioline Laboratories, Inc., et al.*, Civ. Action No. 81-914 (D.N.J., Complaint filed Mar. 3, 1981)]. It was not true that the colors

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that patients regarded the name "CYCLOSPASMOL" as a generic description of the product, rather than as a brand name. *Ives* III at Pet.App. 67a-68a.

On the issue of contributory trademark infringement, the district court noted that Ives had failed to introduce any additional evidence of "illegal substitution" beyond that already found insufficient in *Ives* II. The trial court also rejected the "additional evidence" submitted by Ives showing so-called "mislabeling" during instances of lawful substitution. The Court found that the "mislabeling" had not been shown to have been induced by petitioners; that with only one exception, no pharmacist had intended to profit from the listing of the word "CYCLOSPASMOL" on the label of the lawfully dispensed generic substitute; and all but one pharmacist had actually told the customer that the product was a generic version. The court concluded that the evidence hardly justified an inference that defendants had impliedly invited druggists to "mislabel".[50]

SUMMARY OF ARGUMENT

I.

A. Petitioner Inwood was held liable for "contributory trademark infringement" under Section 32 of the Lanham Act. However, there was no "trademark infringement" for which petitioner could be held liable as a contributor. A few pharmacists were shown by a survey (of dubious statistical relevance) to have *lawfully* dispensed the generic product cyclandelate, and to have labeled or described it as "Generic Cyclospasmol". These pharmacists derived no unfair profit to themselves and caused respondent no injury. The description which they used does not constitute trademark infringement since "Generic Cyclospasmol" is an accurate description of the

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constituted an identification of one source, since the same colors had been available for almost five years from many sources. *Cf.*, Comment, *Product Simulation in the Eighth Circuit*, 57 NEB.L.REV. 91, 139-140 (1978) (hereinafter *Product Simulation*). *See also Ives* II at Pet.App. 48a, n.14.

50. In view of this finding, the District Court did not reach the issue of whether there had been trademark infringement as such in the case of the instances of so-called mislabelling.

contents of the container. In view of the manner in which prescription pharmaceuticals are sold, there was no evidence of any actual or likelihood of confusion. Therefore, such use is not prohibited by the trademark laws.

B. The finding of contributory infringement was in any event erroneous. Such a finding under the applicable legal precedent laid down by the *Ives* II ruling required a showing that petitioner had implicitly suggested to druggists that they engage in an act of trademark infringement and that such acts were widespread. No such showing was made. The mere fact that petitioners used functional capsule colors similar to those of respondent is not a permissible basis for finding liability under Section 32 of the Lanham Act. The decision of the court below found the above-described requisite "suggestion" to druggists in "catalogs", most of which are not even distributed to druggists. The content of these catalogs cannot be reasonably read as suggesting any unlawful conduct. They contain standard trade information of relevance and lawful interest to the parties to whom they are directed. Basing a finding of liability on petitioner's dissemination of this truthful information amounts to an impermissible infringement on the First Amendment right to free speech.

II.

Even assuming that a technical finding of liability can be supported, the Court of Appeals' direction that an injunction be entered prohibiting petitioner from utilizing the capsule colors at issue was improper. The prior decisions of this Court have clearly enunciated a public policy in favor of lawful imitation precluding such an injunction. Moreover, since colors of the prescription pharmaceuticals at issue were found by the District Court to be functional, the decision of the Second Circuit has given respondent an unlawful monopolistic, anti-competitive advantage. In effect respondent's expired patent monopoly has been extended in a significant respect to the detriment of consumers who derive the benefit of lower cost, high quality generic drugs. The Court of Appeals simply declined to adhere to this Court's earlier decisions, which hold that other prophylactic measures, but not a ban on utilization of color, could be applied. The continued force of such earlier rulings should be reaffirmed.

ARGUMENT

I. THE TRUTHFUL COMPARATIVE USE OF A TRADEMARK IN LABELING AND ADVERTISING FORMS NO LEGAL BASIS FOR A FINDING OF TRADEMARK INFRINGEMENT OR CONTRIBUTORY TRADEMARK INFRINGEMENT

Petitioner Inwood respectfully submits that the *Ives* IV holding, which found petitioners liable for contributory trademark infringement under §32 of the Lanham Act should be reversed since neither trademark infringement nor contributory trademark infringement occurred under the applicable legal criteria.

A. THE IVES IV MAJORITY OPINION ERRED IN ASSUMING THAT PHARMACISTS HAD COMMITTED TRADEMARK INFRINGEMENT

It is axiomatic that Inwood and the other petitioners could not have been held liable for contributory trademark infringement unless the acts to which they supposedly contributed constituted trademark infringement in the first instance.[51] Yet, the *Ives* IV decision fails to deal with the threshold issue raised by petitioners below as to whether the supposed "additional evidence" of mislabeling established trademark infringement under the statutory criteria and applicable case law.

As noted by the District Court and Judge Mulligan in his dissent, the pharmacists in question had labeled or orally described the drug products at issue as a generic version of CYCLOSPASMOL [*Ives* II at Pet.App. 60a, 88a-89a].

The trademark laws do not grant a right "in gross" which is protectible against the whole world, in the abstract, without consideration of the facts and circumstances of each particular case. 1 Gilson, TRADEMARK PROTECTION AND PRACTICE, §5.09[3] at 5-76, 5-77 (1980). This basic tenet of

51. *Cf., Reid, Murdoch & Co. v. H.P. Coffee Co.*, 48 F.2d 817 (8th Cir.), *cert. denied*, 284 U.S. 621 (1931); *Stix Products, Inc. v. United Merchants & Mfrs., Inc.*, 295 F.Supp. 479 (S.D.N.Y.1968); *John B. Stetson Co. v. Stephen L. Stetson Co.*, 14 F.Supp. 74 (S.D.N.Y.), *modified*, 85 F.2d 586 (2d Cir.), *cert. denied*, 299 U.S. 605 (1936).

trademark law is central to the Lanham Act's definition of what constitutes trademark infringement:

> "(1) Any person who shall, without the consent of the registrant (a) use in commerce any reproduction . . . of a registered mark. . .*which such use is likely to cause confusion, or to cause mistake, or to deceive;* . . .shall be liable in a civil action for the remedies hereinafter provided." [15 U.S.C. §1114(1)(a)] [emphasis added][52]

While the commentators have identified a split among the Circuits, as yet unaddressed by this Court, as to whether the requisite test of likelihood of confusion, mistake or deceit is one of fact, law or a mixed question of law or fact, *see* J.T. McCarthy, TRADEMARKS AND UNFAIR COMPETITION §23:22 (1973) ("McCARTHY"), there is no dispute that the finding must be made. *Id.*, and cases cited at §23:1 n.1. In this case no such finding was made.

Never before has any court held that the mere description of one product as a generic equivalent of a trademark product is sufficient to constitute trademark infringement under the Lanham Act. To state, as occurred here, that a product is "Generic Cyclospasmol" clearly indicates that it is not the trademarked product but rather a generic version thereof. There was no evidence that patients receiving such a drug product pursuant to a lawful substitution were in any way confused or deceived. Nor has there been any judicial finding of even a likelihood of confusion. Indeed the absence of evidence of actual confusion in cases of lawful substitution after more than five years of marketing by petitioners raises a strong presumption that there is little likelihood of confusion. *See Pignons S.A. De Mecanique De Precision* v. *Polaroid Corp.*, 657 F.2d 482, 490-91 (1st Cir. 1981); *Amstar Corp.* v. *Domino's Pizza, Inc.*, 615 F.2d 252, 263 (5th Cir.), *cert. denied*, 449 U.S. 899 (1980).

That a comparative identification of one product by reference to another's trademark does not give rise to liability was established by this Court in the landmark case of *Saxlehner* v. *Wagner*, 216 U.S. 375 (1910), where Justice Holmes recognized that:

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52. The same criteria are also found in §32(1)(b) of the Act [15 U.S.C. §1114(1)(b)].

> "[t]he real intent of the plaintiff's bill, it seems, is to extend the monopoly of her type of bitter water, by preventing manufacturers from telling the public in a way that will be understood what they are copying and trying to sell. But the plaintiff has no patent for the water, and the defendants have a right to reproduce it as nearly as they can. They have a right to tell the public what they are doing and to get whatever share they can in the popularity of the water by advertising that they are trying to make the same article and think that they succeed . . .By doing so they are not trying to get the good will of the name, but the good will of the goods." *Id.* at 380.

The clear precedent prior to *Ives* IV established that the use of such written and oral terms[53] "generic Cyclospasmol" or "same as Cyclospasmol" or "equivalent to Cyclospasmol" by the pharmacist did not constitute an infringement of the CYCLOSPASMOL trademark. *See Champion Spark Plug Co.* v. *Sanders,* 331 U.S. 125, 128 (1947); *Prestonettes, Inc.* v. *Coty,* 264 U.S. 359, 368-369 (1924); *Societe Comptoir de L'Indus., etc.* v. *Alexander's Dept. Stores,* 299 F.2d 33, 36 (2d Cir. 1962); *Taylor Instrument Companies* v. *Fawley-Brost Co.,* 139 F.2d 98, 102-103 (7th Cir. 1943), *cert. denied,* 321 U.S. 785 (1944); *Electric Auto-Lite Co.* v. *P&D Mfg. Co.,* 78 F.2d 700, 702-703 (2d Cir.), *cert. denied,* 296 U.S. 648 (1935); *Geisel* v. *Poynter Products,* 295 F.Supp. 331, 352-354 (S.D.N.Y. 1968).[54]

Consideration of the question of trademark infringement in the context of a product dispensed by a pharmacist for a patient begins with a recognition that the patient does not purchase a prescription drug product by unilaterally selecting the drug product of his or her choice. As found by the district court, patients do not perceive the significance of a trademark as identifying source for prescription drugs, since brand-name promotion is limited exclusively to professionals:

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53. Oral explanations are clearly sufficient and in fact have sometimes been required to avoid liability for trademark infringement. *See, e.g., Coca-Cola Co. v. Dorris,* 311 F.Supp. 287 (E.D.Ark. 1970).

54. *See also Smith v. Chanel, Inc.,* 402 F.2d 562, 564 (9th Cir. 1968); *Viavi Co. v. Vimedia Co.,* 245 F. 289, 292 (8th Cir. 1917), *cert. denied,* 246 U.S. 664 (1918); McCARTHY at §25.14 at 192.

> "Ives argues that because 'Cyclospasmol' is a trademark which only it can use, a patient who identifies a cyclandelate capsule as 'Cyclospasmol' is necessarily indicating that he believes the drug comes from a single source. But even as to the trademark itself we must 'remember that relief always depends upon the idea that no man shall be allowed to mislead people into supposing that his goods are the plaintiff's, and that there can be no right or remedy until plaintiff can show that at least presumptively this will result.' *Bayer Co.* v. *United Drug Co.*, 272 F. 505, 509-510 (S.D.N.Y. 1921) (L.Hand, J.)"
>
> "No doubt to physicians and pharmacists the word 'Cyclospasmol' signifies a source. But there is no reason to suppose this is so as to patients. They have not been the target of the sales campaign, and they play no role in choosing what drug to buy. Nothing in the record suggests that they 'understand by the word anything more than a kind of drug to which for one reason or another they [have] become habituated.' *Id.* at 510. Such patients as read their prescriptions do not attribute to Cyclospasmol 'any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic value.' *Id.*" *Ives* III at Pet.App. 66a-67a.

See Bayer Co. v. *United Drug Co.*, 272 F. 505 (S.D.N.Y. 1921); *Syntex Laboratories, Inc.* v. *Norwich Pharmacal Co.*, 315 F.Supp. 45, 49 (S.D.N.Y. 1970)[55], *aff'd*, 437 F.2d 566 (2d Cir. 1971). As noted by Professor McCarthy:

> "Some products, such as prescription drugs, may be sold only to or through a professional class of

55. In *Syntex*, Judge Mansfield noted that, "[e]xcept for the remote possibility of confusion on the part of a patient who has a quantity of both products, prescribing physicians and dispensing pharmacists constitute the class within which confusion between plaintiff's and defendant's products is of concern to us." *Id.* at 49. *Cf., Pfizer & Co. v. Generic Formulae, Inc.*, 275 F.Supp. 421, 423 (E.D.N.Y. 1967). *See also* A. Seidel, S. Dubroff, and E. Gonda, TRADEMARK LAW AND PRACTICE ¶16.08 at 424 (1963); CALLMAN §83.1(m) at 195 (Supp. 1980).

> customers. Such professionals may be trained to recognize long and complicated terms as the generic name of a product, whereas the ordinary customer would unconsciously reject a complicated term and long for some short, easy to remember generic name. For example, medical doctors are familiar with the long, tongue-twisting generic terms such as dextro-amphetamine sulfate, or oxytetracycline. But the consumer may reject such terms and seize upon what the seller considers a trade mark—such as Dexedrine or Terramycin. The consumer may consider such short terms as the generic 'name' of the drug, whereas doctors are trained to know that Dexedrine and Terramycin are merely brand names—legal trademarks of only one producer of the drug." McCARTHY at §12.2B at 407.[56]

In arguing that the acts of the pharmacists constituted trademark infringement, Ives was in effect claiming that their trademark functions as such to patients as a class—contrary to historical experience in the industry. It was therefore error for the Second Circuit to assume *sub silentio* that any appearance of the word "CYCLOSPASMOL" on the label of a dispensing container *per se* produced patient confusion.

The "additional evidence" demonstrated not only an absence of actual confusion, but in fact the "unlikelihood" of confusion: (1) The prescription presented to the pharmacists expressly affirmed that substitution was permissible; (2) almost all of the pharmacists did not use the word "CYCLOSPASMOL' alone, but explained, either orally or in writing, that a generic product was being dispensed; (3) each patient received the drug authorized by the physician and the New York drug substitution law; (4) all but one pharmacist charged an appropriately reduced generic price; and (5) Ives suffered no competitive injury from the sales. To classify these instances as trademark infringement is to exalt form over substance.[57]

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56. *See also* Tr. 226-227, J.A. 161a; Premo Ex. 63 at 58-59, Tr. 760, J.A. 461a. *Cf., DuPont Cellophane Co. v. Waxed Products Co.*, 85 F.2d 75, 84 (2d Cir.), *cert. denied*, 299 U.S. 601 (1936).

57. In the context of lawful substitution, an interesting jurisdictional question is raised concerning the interstate commerce requirement of §32(1)(a) of the Lanham Act. *See* Annotation, 15 ALR Fed 368 (1973).

It appears that the *Ives* IV majority was oblivious to the distinction under the trademark law between utilizing a trademark as a deceptive and misleading source of origin and the innocent use by the pharmacist, as shown by the survey which comprised the "additional evidence" introduced by Ives.[58]

It is important to emphasize that the action of these pharmacists were not characterized as "mislabeling" because they falsely identified the product as "Generic Cyclospasmol". To the contrary, this term accurately described the product. The pharmacists' "offense" was that they varied from the technical labeling requirements of the New York drug substitution law in not listing the unfamiliar generic name and/or the name of the generic manufacturer [Tr. 813-814, J.A. 270a]. Having charged the generic price, the pharmacists could not have made such omissions for any ulterior or unlawful motive [Tr. 820, J.A. 273a]. Ives suffered no loss of sales from the action of the pharmacist in filling the prescription correctly.

Ives IV has thus erroneously transformed a technical violation of the New York drug labeling law into a finding of *per se* trademark infringement. Under applicable trademark principles, infringement simply did not occur. Infringement can only be of the public's right to be free of confusion and the markholder's right to be free of unfair competition—neither was shown to have occurred here. Infringement does not exist, even though the marks are identical and the goods very similar, where the evidence indicates no likelihood of confusion. *See Application of E.I.DuPont & De Nemours & Co.*, 476 F.2d 1357 (CCPA 1973). It is respectfully submitted that the Court of Appeals' finding of infringement is erroneous and must be reversed.

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58. For example, the opinion states that 2 out of 25 pharmacists in a survey conducted by Premo, demonstrating a complete absence of illegal substitution, had nevertheless labeled the generic cyclandelate as CYCLOSPASMOL [*Ives* IV at Pet.App. 81a-82a, n.7]. However, a stipulation entered into in the District Court expressly states that the two vials in question were labeled "Cyclospasmol Generic," and the pharmacists charged the appropriately lower generic price [Pl.Ex. 142, Tr. 726-731, J.A. 375a-382a].

B. THE IVES IV OPINION ERRONEOUSLY APPLIED THE DOCTRINE OF CONTRIBUTORY TRADEMARK INFRINGEMENT AND IN SO DOING INTERFERED WITH PETITIONERS' EXERCISE OF THEIR FIRST AMENDMENT RIGHT TO FREE SPEECH

The Second Circuit's finding that petitioners implictly suggested that pharmacists engage in trademark infringement is erroneous and stretches the doctrine of contributory trademark infringement to a point where it threatens competition in the field of prescription drugs.

The Lanham Act makes express provision in §32 for primary trademark infringement. It also makes an express provision for a type of contributory trademark infringement not at issue here, *i.e.*, where a party affixes an infringing mark to goods which are intended for subsequent infringing use in interstate commerce [15 U.S.C. §1114(1)(b)]. However, the statute makes no express provision for the species of contributory trademark infringement at issue in this case. *See* Cooper, *Trademark Aspects of Pharmaceutical Product Design*, 70 TMR 1, 39-40 (1980).

It is well-established that liability for contributory trademark infringement may nevertheless be extended beyond those who affix the infringing mark or sell goods with such a mark. Persons who knowingly cooperate in illegal and tortious activity by encouraging others to engage in trademark infringement have been found liable. This category of contributory trademark infringement has historically developed as a matter of common law outside the direct provisions of the Lanham Act.[59] Prior to the decision of Judge Mansfield below, no court had ever held that this type of contributory trademark

59. *See, e.g., Stetson*, 85 F.2d at 588; *Andrew Jurgens Co. v. Bonded Products Corp.*, 21 F.2d 419, 424 (2d Cir. 1927), *cert. denied*, 275 U.S. 572 (1928); *Cuervo v. Jacob Henkell Co.*, 50 F. 471 (S.D.N.Y. 1892). *See also Corning Glass Works v. Jeanette Glass Co.*, 308 F.Supp. 1321 (S.D.N.Y.), *aff'd per curiam*, 432 F.2d 784 (2d Cir. 1970). *But see* Judge (later Justice) Minton's holding in *Zangerle & Peterson Co. v. Venice Furniture Novelty Mfg. Co.*, 133 F.2d 266 (7th Cir. 1943).

infringement was actionable directly under §32 of the Lanham Act.[60]

Whether or not Judge Mansfield was correct in reading the doctrine of contributory trademark infringement directly into §32 of the Lanham Act, the criteria established by Judge Friendly in *Ives* II were the guidelines and framework within which the case was tried by the District Court, and pursuant to which Judge Mansfield applied and conducted appellate review. The two-prong standard articulated in *Ives* II was as follows:

> "The authorities later reviewed indicate to us that a manufacturer or wholesaler would be liable under Section 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described. The proper criteria are stated in *Coca-Cola Co.* v. *Snow Crest Beverages, . . .*" *Ives* II at Pet.App. 35a.

No claim was ever made that any of the petitioners had *continued* to sell capsules to a druggist after learning or knowing that the druggist was actually engaging in trademark infringement. *Ives* III at Pet.App. 59a, *Ives* IV at Pet.App. 87a (Mulligan, J.). The sole issue, therefore, was whether petitioners had suggested, even if only by implication, that druggists engage in such conduct.

Under this prong, mere imitation of color configuration without more is not sufficient to establish liability. *See William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526, 531 (1924); *Nugrape Co. of America* v. *Glazier*, 22 F.2d 596, 597 (5th Cir. 1927); *Smith, Kline & French Laboratories* v. *Waldman*, 69 F.Supp. 646, 648 (E.D.Pa. 1946); *Coca-Cola Co.* v. *Snow Crest*

60. *Ives* II, for example, refers to the leading decision of *Coca-Cola Co. v. Snow Crest Beverages*, 64 F.Supp. 980 (D.Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947). In that case, contributory infringement was clearly raised as a matter of common law rights, rather than as a federal cause of action under §32. *Cf., Stix Products, Inc. v. United Merchants & Mfrs., Inc., supra.*

Beverages, 64 F.Supp. at 990.[61] For a finding of liability, there must be some actual suggestion, express or implied, that the infringer engage in the unlawful conduct.[62] *See, e.g., Smith, Kline & French Laboratories* v. *Clark & Clark*, 157 F.2d 725 (3d Cir.), *cert. denied*, 329 U.S. 796 (1946).

Applying this standard, Judge Friendly in *Ives* II found:

> "[T]he court was justified in concluding that Ives failed to adduce the quantum of proof necessary to require issuance of a temporary injunction for contributory infringement even on what we deem the proper standard of liability under §32. Ives' proof was limited to 15 instances of improper substitution and defendants conceded only that the identity of color made this easier if a druggist were so inclined." *Ives* II at Pet.App. 35a-36a.
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> * * *
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> "As noted above, the evidence of improper substitution was limited to 15 prescriptions. Discovery and trial might show that the practice was much more widespread or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices." *Id.* at Pet.App. 53a.

At trial, Ives abandoned all efforts to show that "illegal substitution" of cyclandelate[63] was more widespread than the

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61. *See also Swank, Inc. v. Anson, Inc.*, 196 F.2d 330 (1st Cir. 1952); *Zangerle & Peterson Co. v. Venice Furniture Novelty Mfg.Co., supra; Famolare, Inc. v. Melville Corp.*, 472 F.Supp. 738 (D.Haw. 1979), *aff'd without opinion*, 652 F.2d 62 (9th Cir. 1981); *Pezon et Michel v. Ernest R. Hewin Associates, Inc.*, 270 F.Supp. 423 (S.D.N.Y. 1967); *Mattel, Inc. v. Goldberger Doll Mfg. Co., Inc.*, 200 F.Supp. 517 (E.D.N.Y. 1961). *Cf., Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964); and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964).

62. Ives had argued in the appeal of *Ives* I that mere copying of color was sufficient to establish liability under §32, as well as secondary meaning under §43(a). This was rejected. *Ives* II at Pet.App. 50a-51a.

63. *i.e.*, a prescription which by law may be filled only with the specific brand product is filled instead with a different product. *See* Pet.App. at 112a-120a.

original evidence submitted. *Ives* III Pet. at App. 59a.[64] A survey to determine the extent (if any) of illegal substitution of cyclandelate could easily have been done [Tr. 120a, J.A. 106a-107a; Tr. 568, J.A. 204a], but the record shows that Ives deliberately chose not to do so [Tr. 86, J.A. 145a].[65] Instead, Ives attempted to show that in cases of *lawful* substitution, the word Cyclospasmol was sometimes applied to the dispensing container. Ives thus sought to satisfy Judge Friendly's requirement that the trademark infringement be "much more widespread" solely with reference to lawful substitution, and conducted its survey attempting to provide such "additional evidence" as previously described.

In *Ives* IV, Judge Mansfield accepted Ives' claim that the "additional evidence"—described as evidence of "mislabeling"—was sufficient and that petitioners could thereby be found liable for having implicitly suggested that pharmacists engage in such "mislabeling". According to the majority opinion, the criteria laid down in *Ives* II were satisfied as follows:

> "The additional evidence introduced by Ives at trial was clearly sufficient to establish a §32 violation. By using capsules of identical color,

64. At trial, the following colloquy took place:

> "THE COURT: I take it that you are not — I think I may have asked you this — you are not going to offer any testimony of shopping that shows an illegal substitution."
>
> "MS. DRISCOLL: Not other than those we had on the initial motion." Tr.394. [*See also* Tr. 86, J.A. 145a].

65. The evidence of illegal substitution was thus confined to a total of either four, or at most nine, pharmacies. *See* n.25 *supra*, and accompanying text. In confusing dicta, Judge Mansfield nevertheless describes "illegal substitution" as widespread. At the request of Ives, judicial notice was taken of six indictments of pharmacies, which were handed down after the trial was completed. *Ives* IV at Pet.App. 84, n.5. These pharmacies were alleged to have illegally substituted cyclandelate. If judicial notice was intended as a means of filling a huge gap in the evidence below, it was clearly improper. *See Goland v. CIA*, 607 F.2d 339, 371-372 (D.C.Cir. 1978), *cert. denied*, 445 U.S. 927 (1980); F.R.Civ.P. 60(b). *Cf., United States v. Lowell*, 649 F.2d 950 (3d Cir. 1981). We cannot believe, however, that Judge Mansfield seriously intended that by raising the total number of pharmacists to fifteen, at most, that illegal substitution of cyclandelate could be characterized as "widespread". There are more than 140,000 pharmacists in the United States. *See* 20 APhARMACY WEEKLY at 170 (November 4, 1981). *See also Ives* IV at Pet.App. 90a (Mulligan, J.).

> size and shape, together with a catalog describing their appearance and listing comparative prices of CYCLOSPASMOL and generic cyclandelate, appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally for Ives' trademarked CYCLOSPASMOL[66] or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage. This amounted to a suggestion, at least by implication, that the druggists take advantage of the opportunity to engage in such misconduct." *Ives* IV at Pet.App. 82a.

No such implicit suggestion can be found in the so-called catalogs. As regards Inwood, the statement that its price sheet amounted to a suggestion by implication that *druggists* take advantage of an opportunity to engage in misconduct defies rational analysis. Even assuming that this price sheet would have been seen by some druggists, the mere advertising of the availability of products for sale, a listing of the product to which they were generically equivalent and a description of the appearance of all products could hardly amount to an "implication" to druggists that they engage in misconduct. On the contrary, it simply was a notification that the product was available for sale at the prices stated. The manufacturers'

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66. This is the first of various instances where Judge Mansfield comingles the concept of "illegal substitution" with that of technical "mislabelling". The additional evidence referred to in this paragraph of the opinion and described earlier by Judge Mansfield dealt only with *mislabeling* and not illegal substitution. There are other troublesome factual errors in the opinion. As part of the "additional evidence", Judge Mansfield refers to "9 out of 17 instances" of alleged mislabeling. We are unable to find any testimony in the Record identifying the seventeen instances of which these nine are said to be a part. Significantly, no such reference is found in Judge Nickerson's opinion. The *Ives* IV opinion also states that many generic drugs are successfully marketed in capsules or tablets that do not copy Ives' product. The court lists one example. *See Ives* IV at Pet.App. 85a. The actual evidence, was that the relied-upon example was the only such product [Tr. 20]. There were no others and, as discussed, one company which had tried to market in a different color was forced to discontinue it because the unfamiliar color was not acceptable to its hospital customers. Another error with respect to the characterization of the testimony of an *Ives* witness, Lawlor, as a "witness called by appellees" was corrected. *See Ives* IV at Pet.App. 85a, 93a. After the correction, the statement loses its force.

catalogs did not, as Judge Mansfield suggests, list comparative prices of CYCLOSPASMOL and generic cyclandelate. Some of the wholesaler catalogs did so simply because these companies offered both products for sale. Moreover, as noted by Judge Mulligan:

> "[I]t was common in the industry to list the generic drug next to the brand name drug . . . Thus, it would seem that juxtaposition of the generic and brand-name drug would be imperative for generic manufacturers to compete effectively." *Ives* IV at Pet.App. 90a, n.4. *See also* Tr. 657-659, J.A. 225a-227a.

The most that Judge Mansfield could state in describing petitioners' price sheets was that they were "pro-substitution" catalogs. *Ives* IV at Pet.App. 76a. Assuming *arguendo* that this description is accurate, it highlights the error made in the court below. In some of the early cases, companies dealing directly with pharmacies were found to have advertised one or two products in their literature which emphasized similarity of color *(e.g.,* "Color Guaranteed") and differences in price where the brand-name product was not offered for sale by the company.[67] Additional illicit suggestions such as "keep the substitution cards out of sight" were also found.[68] These cases occurred at a time when substitution was unlawful in almost all states and generic prescribing was extremely limited [Tr. 765-766, J.A. 263a]. Under those circumstances, a finding that an isolated company's action was "pro-substitution" might fairly be construed as an implied suggestion to unlawfully substitute. Today, as previously noted, the situation is far different. Even if petitioners' catalogs are "pro-substitution", that can be no basis for an implication that unlawful criminal activity is suggested thereby.[69]

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67. *See, e.g., Ross-Whitney Corp. v. Smith, Kline & French Laboratories,* 207 F.2d 190 (9th Cir. 1953); *Smith, Kline & French Laboratories v. Broder,* 125 U.S.P.Q. 299 (S.D.Tex. 1959); *Smith, Kline & French Laboratories v. Heart Pharmaceutical Corp.,* 90 F.Supp. 976 (S.D.N.Y. 1950); *Martin H. Smith Co. v. American Pharmaceutical Co.,* 270 N.Y. 184 (1936).

68. *See Upjohn Co. v. Schwartz,* 246 F.2d 254, 260-61 (2d Cir. 1957).

69. Contrary to the statements in the *Ives* IV opinion, the instances of mislabeling did not constitute any economic advantage to the druggists or petitioners.

Instructive in this regard is Judge Wyzanski's decision in *Coca-Cola Co.* v. *Snow Crest Beverages, supra,* which describes a situation somewhat comparable to the case at bar. The Coca-Cola Company there attempted to hold a competitor liable as a contributory trademark infringer because patrons of certain bars, upon requesting a drink consisting of or supposedly including Coca-Cola, were in fact receiving a substitute cola marketed by the defendant. Presumably the substitution might not have occurred if the colors of the colas had been different.[70] In *Snow-Crest,* as Ives does here, Coca-Cola argued that it was not seeking to prohibit competition from another cola drink, but merely to hold the competitor liable for the acts of bartenders in unlawfully substituting the competitive cola to the ultimate customer. In what has become the classic and definitive answer to Ives' argument, Judge Wyzanski held:

> "But in the case at bar plaintiff seems to urge that defendant's obligation goes further. Plaintiff appears to contend that once a defendant has knowledge that some customers of bars specifically order 'rum (or whiskey) and Coca-Cola' and that there are in all probability some rogues in the bar business as in other businesses, the defendant has a duty either (a) not to sell to any bar a cola until defendant first creates for that cola special consumer demand, or (b) at least not sell a cola to a bar before defendant has particularly cautioned the bar to be scrupulous against substitution. The law does not go that far." 64 F.Supp. at 989.

The record here shows far *fewer* instances of illegal substitution of cyclandelate than those which were present in *Snow Crest. See Id.* at 986-987. The admitted fact that some unscrupulous pharmacists will engage in illegal substitution should not be a basis for imposing contributory liability on

70. Coca-Cola for many years had attempted without success to compel other companies to use a different coloring for the cola drinks. Almost uniformly, the courts, including this Court, held that the public, having become accustomed to the color of cola as found in the Coca-Cola beverage, could not be deprived of the familiar color when the same product was sold by a competitor. *See Coca-Cola Co. v. The Koke Company of America,* 254 U.S. 143 (1920). *See also* Note, *Unfair Competition and the Doctrine of Functionality,* 64 COLUM. L REV. 544, 558, n.94 (1964) (hereinafter "Functionality").

Inwood or the other petitioners[71]. That others in a minority of instances will label lawfully dispensed generic products as Cyclospasmol without any ill motive or prejudice to Ives should not support a hindsight conclusion that this inadvertent conduct was implicitly suggested by petitioners in price sheets and catalogs. *Cf. Fortnightly Corp.* v. *United Artists Television, Inc.*, 392 U.S. 390, 397 (1968).[72]

A very serious constitutional issue is also raised by the Second Circuit's attempt to utilize the exercise of petitioners' commercial free speech rights as a basis for subjecting them to liability for contributory infringement. This Court has noted that constitutional free speech protections apply to pharmacists when they convey price information to consumers.[73] *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). *See also Bates* v. *State Bar of Arizona*, 433 U.S. 350 (1977). The same right applies to petitioners' attempts to market a product in competition with that of Ives. Significantly, cyclandelate is a drug for which

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71. *See Famolare, Inc. v. Melville Corp.*, 472 F.Supp. at 74/. *See also* McCARTHY,§25.2 at 175 (doctrine of contributory infringement does not demand that defendants refuse to sell to dealers who merely might pass-off its goods).

72. The doctrine of contributory trademark infringement first originated as a derivative of the same doctrine in the field of patents. *Howard Dustless Duster Co. v. Carleton*, 219 F. 913, 915 (D.Conn. 1915). Under the patent law, it is an absolute defense to a charge of contributory patent infringement if the contributorily infringing item is a staple item of commerce having a substantial non-infringing use. 35 U.S.C. §271(b). *See also Henry v. A.B. Dick Co.*, 224 U.S. 1, 48 (1912). To hold otherwise, this Court has observed, would "block the wheels of commerce." *Id.* There can be no doubt of the substantial non-infringing use of petitioners' products in the marketplace. In fact, the primary and overwhelming majority use of petitioners' products is by pharmacists who commit no act of which Ives can complain. *See* Callman's discussion of the substantial non-infringing use doctrine in the context of trademarks. CALLMAN, §82.1(m) at 203-206 (Supp. 1980). *See also* discussion in *Universal City Studios, Inc. v. Sony Corp. of America*, 659 F.2d 963 (9th Cir. 1981). It surely cannot be the law that under the doctrine of contributory trademark infringement, Ives is entitled to an even greater degree of protection after its patent has expired.

73. In the context of prescription pharmaceuticals, the capsule colors themselves emerge as a form of speech. *See* discussion, *supra*. Petitioners cannot constitutionally be compelled by way of capsule color to make a negative and inaccurate statement about their own product. Their free speech rights should further protect the truthful statement which identity of color implies, *i.e.*, that petitioners' products are not therapeutically different from those previously taken by the patient.

substitution is permissive rather than mandatory. Petitioners' price sheets and catalogs indicate the truthful information that their products are generic versions of the brand-name product and thereby eligible for permissive substitution.

In recognition of this Court's affirmation of the right to commercial free speech, lower courts have recognized that the Lanham Act should not be construed in a manner that would bring it into conflict with First Amendment interests. *See Stop the Olympic Prison* v. *U.S. Olympic Committee,* 489 F.Supp. 1112, 1124 (S.D.N.Y. 1980). *See also Triangle Publications, Inc.* v. *Knight-Ridder Newspapers, Inc.,* 445 F.Supp. 875, 884 (S.D. Fla. 1978), *aff'd on other grounds,* 626 F.2d 1171 (5th Cir. 1980) (court observed that comparative advertising which uses another's trade name "is in harmony with the fundamental objectives of free speech and free enterprise in a free society."); *Fur Information and Fashion Council, Inc.* v. *E.F. Timme & Son, Inc.,* 364 F.Supp. 16, 22 (S.D.N.Y. 1973), *aff'd on other grounds,* 501 F.2d 1048 (2d Cir.), *cert. denied,* 419 U.S. 1022 (1974).[74]

The Second Circuit's holding has placed generic drug companies on the horns of a dilemma. If they choose to engage in the standard forms of advertising long prevalent in the industry, they now run the risk that, under the Second Circuit opinion, they may be automatically liable for contributory trademark infringement and thereby lose the right to market an important functional and competitive feature of their product.[75] If they choose not to advertise under this threat of liability, then, as against them, the competitor's trademark (as Justice Holmes observed) has been impermissibly extended to the product itself. *See Saxlehner* v. *Wagner,* 216 U.S. at 380. First Amendment rights should not be so cavalierly restricted by the expansive approach to contributory trademark infringement taken by the

74. *Cf., Rosemont Enterprises, Inc. v. Random House, Inc.,* 366 F.2d 303, 311 (2d Cir. 1966) (Lumbard, J., concurring), *cert. denied,* 385 U.S. 1009 (1967); *Time, Inc. v. Bernard Geis Associates,* 293 F. Supp. 130, 145 (S.D.N.Y. 1968).

75. The extensive evidence of functionality discussed *supra* rebuts any supposed inference that petitioners intended the identity of capsule color as "an implied suggestion." *See Famolare, Inc. v. Melville Corp., supra.* Whether or not Judge Mansfield was convinced on the question of functionality cannot belie the fact that identical colors were used consistent with the long-standing industry practice.

lower court. It is respectfully submitted that the finding of contributory trademark infringement is thus factually erroneous, legally unsound, and constitutionally impermissible.

II. SECTION 32 OF THE LANHAM ACT MAY NOT GRANT A TRADEMARK OWNER MONOPOLY RIGHTS IN THE COLOR OF ITS PRODUCT

Although the holding of *Ives* IV is caught up in the complexities of trademark infringement and contributory trademark infringement, the end result is remarkably clear. The court held that as a remedy for the supposed violation of law, Ives must be granted a perpetual monopoly on the colors blue and blue/red for cyclandelate and an injunction to that effect was promptly entered by the District Court. *See Ives* V at Pet.App. 96a, 98a. Judge Mansfield explained that such an injunction would be the "simplest way" to grant plaintiff relief. *Ives* IV at Pet.App. 86a.

In other contexts, simplicity undoubtedly has its virtue. Here, the sought-after simplicity directly contravenes almost 100 years of controlling precedent. *See Coats* v. *Merrick Thread Co.*, 149 U.S. 562, 573-574 (1893); *A. Leschen & Sons Rope Co.* v. *Broderick & Bascom Rope Co.*, 201 U.S. 166, 171 (1906); *Schlitz Brewing Co.* v. *Houston Ice Co.*, 250 U.S. 28, 29-30 (1919); *Coca-Cola* v. *The Koke Company of America*, 254 U.S. at 147; *William R. Warner* v. *Eli Lilly & Co.*, 265 U.S. at 531; *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111, 121-123 (1938); *Sears*, 376 U.S. at 230-233; *Compco*, 376 U.S. at 239.[76]

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76. *Accord, Diamond Match Co. v. Saginaw Match Co.*, 142 F. 727, 729 (6th Cir. 1906), *cert. denied*, 213 U.S. 598 (1908); *Newcomer & Lewis v. J.A. Scriven Co.*, 168 F. 621 (6th Cir.), *cert. denied*, 214 U.S. 518 (1909); *Rice-Stix Dry Goods Co. v. J.A. Scriven Co.*, 165 F. 621 (6th Cir. 1908), *cert. denied*, 223 U.S. 708 (1911); *L.E. Waterman Co.*, 34 App.D.C. 185 (D.C.Cir. 1909); *Samson Cordage Works v. Puritan Cordage Mills*, 211 F. 603 (6th Cir. 1914); *Viavi Co. v. Vimedia Co.*, 245 F. 289 (8th Cir. 1917), *cert. denied*, 246 U.S. 664 (1918); *Zangerle & Peterson Co.*, 133 F.2d at 270; *Smith, Kline & French Laboratories v. Clark & Clark*, 157 F.2d at 731; *Campbell Soup Co. v. Armour & Co.*, 175 F.2d 795, 798-799 (3d Cir.), *cert. denied*, 338 U.S. 847 (1949); *Tast-T-Nut Co. v. Variety Nut & Date Co.*, 245 F.2d 3, 6-7 (6th Cir. 1957); *Upjohn Co. v. Schwartz*, 246 F.2d at 256; *Norwich Pharmacal Co. v. Sterling Drug Inc.*, 271 F.2d at 572-573; *Unistrut Corp. v. Power*, 280 F.2d 18, 23-24 (1st Cir. 1960); *Plastilite Corp. v. Kassnar Imports*, 508 F.2d 824 (CCPA 1975). *Cf., Keene Corp. v. Paraflex Industries, Inc.*, 653 F.2d 822, 827-828 (3d Cir. 1981); *International Order of Job's Daughters v. Lindeburg & Co.*, 633 F.2d 912 (9th Cir. 1980), *cert. denied*, ____ U.S. ____, 69 L.Ed.2d 956 (1981).

The central principle of the foregoing cases is that free and open competition necessarily requires that "imitation" be encouraged and that the right to imitate, absent legitimate patent, trademark or copyright protection, cannot be constricted:

> "Sharing in the goodwill of an article unprotected by patent or trademark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested." *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. at 122.

See also American Safety Table Co. v. *Schreiber*, 269 F.2d 255, 272 (2d Cir.), *cert. denied*, 361 U.S. 915 (1959); Stern & Hoffman, *Public Injury and the Public Interest: Secondary Meaning in the Law of Unfair Competition*, 110 U.PA.L.REV. 935, 942 (1962); *Product Simulation*, 57 NEB. L.REV. at 91-92.

A competing philosophy has emerged which expounds the exact opposite of the principles noted above. Articulated most forcefully in a string of decisions rendered in the United States District Court for the District of New Jersey, this view asserts that there is a duty upon "second comers" to make their product appear as "different as possible" from that of that of their competitors.[77] The "simplicity" preference ennunciated in *Ives* IV accepts by implication the rationale (although not the legal holdings) of these cases.[78]

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77. *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980) *aff'g*, 481 F.Supp. 1184 (D.N.J. 1979); *Biocraft Laboratories, Inc. v. Merck & Co., Inc.*, ___ F.Supp. ___, Civ. Action No. 77-693 (D.N.J. Oct. 2, 1980); *Boeringer-Ingelheim GmbH v. Pharmadyne Laboratories*, 211 U.S.P.Q. 1163 (D.N.J. 1980); *Hoffman-La Roche v. Premo Pharmaceutical Laboratories, Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980); *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc., supra. See also Johnson & Johnson v. Quality Pure Mfg. Co.*, 484 F. Supp. 975, 982 (D.N.J. 1979).

78. The cases cited above have reached their result upon alleged violations of §43(a) of the Lanham Act [15 U.S.C. §1125(a)] and an expansive view of the concept of secondary meaning and the scope of the New Jersey state law of unfair competition. These legal issues are not before this Court.

The far-reaching consequences of the "different as possible" rule as a restraint on free competition are self-evident.[79] Some of the commentators have taken note of and seriously questioned the strength of the analysis which forms the basis of this protectionist trend. *See* Stern, *The Persantine, Librax & Elavil Decisions: Colourful Brands of Drugs*, 2 EUR. INTEL. PROP. REV. 59 (1981); CALLMAN at §82.1(m) at 195-206 (Supp. 1980).

The importance of the overall issue notwithstanding, the issues raised here relate to the following specific framework:

(1) The product at issue is a prescription drug for which patent protection has expired;

(2) During the life of the patent, patients receiving cyclandelate inevitably become accustomed to the color configuration used by Ives by virtue of its exclusive monopoly;

(3) Irrespective of patent (*e.g.*, the blue/red 400-mg. capsule), patients become familiar with a particular color configuration by virtue of long-term therapy;

(4) No secondary meaning has been found for either color configuration;

(5) Should the law permit the generic competitor to sell the prescription drug in the color to which the patient has become accustomed or should the law require it to use a color which is as different as possible?

(6) Should the Court now abandon its historic rule that a prohibition on copying is not permissible absent express federal statutory protection?

Petitioner respectfully submits that this Court should reaffirm the traditional rule that, whatever the theory of liability,

79. For example, in a variant of the same theme, one district court has gone so far as to hold that an amusement center trading under the name "Jellibeans" has the right to prevent a competitor from opening a similar establishment using the name "Lollipops." *Jellibeans, Inc. v. Skating Clubs of Georgia, Inc.*, ___ F.Supp. ___ No. C-80-1689A (N.D.Ga. May 19, 1981), reported in 540 BNA Patent, Trademark & Copyright Journal, A-5 (August 6, 1981).

under these circumstances the utilization of similar capsule colors may not be enjoined. *William R. Warner* v. *Eli Lilly & Co., supra; Norwich Pharmacal Co.* v. *Sterling Drug, supra; Upjohn Co.* v. *Schwartz, supra; Smith, Kline & French Laboratories* v. *Clark & Clark, supra; Smith, Kline & French Laboratories* v. *Waldman, supra. Cf., Sears, supra,* and *Compco, supra.*

First, the lower courts have too quickly dismissed the problem inherent in any sanction for monopoly of color. It is true that it is easy enough for one company to distinguish its capsule colors from those of a single competitor, but what happens when each subsequent manufacturer must utilize different colors for each dosage strength and still be as different as possible from every other color configuration of every other company making the same drug product?

> "Thus, a producer might market a red-and-white capsule to indicate 5 mg. strength, a red-and-green capsule for 10 mg. dosage and a red-and-yellow capsule for a 25 mg. strength. . . . Consider the confusion if a rival produced a generic red and yellow for 5 mg., red and white for 10 mg., and red and green for 25 mg. content? Then multiply the confusion with the other generic producers who may use the constant color red but vary the other colors for the different dosages of their product." *See* CALLMAN, §82.1(m) at 196-197 (Supp. 1980).

Second, the evidence of functionality, as found by the District Court, should as a matter of law and public policy preclude any company from monopolizing the colors of a prescription drug. The prior cases have recognized that a public which becomes accustomed to a particular color configuration should be entitled to receive the same configuration from a competing company at least in the absence of secondary meaning. *Pagliero* v. *Wallace China Co.*, 198 F.2d at 343. *See also Keene* v. *Paraflex, supra; Bliss* v. *Gotham Industries, Inc.*, 316 F.2d 848, 855 (9th Cir. 1963); *Application of Deister Concentrator Co.*, 289 F.2d 496, 505 (CCPA 1961); *Norwich Pharmacal Co.* v. *Sterling Drug, Inc., supra; J.C. Penney Co.* v. *H.D. Lee Mercantile Co.* 120 F.2d 949, 954 (8th Cir. 1941);

RESTATEMENT OF TORTS, §742 (1938); *Functionality*, 64 COLUM. L.REV. at 558-563.

Functionality of capsule colors was demonstrated in that patients would be "put off" by different colors, lawful substitution would be impeded, therapeutic efficacy could be compromised in terms of the psychological placebo function, and emergency and dosage identification would be hindered. Due to these factors, the prior cases, even after a finding of liability, refused to grant monopoly color rights to brand-name manufacturers and limited relief to other appropriate and less drastic measures. *William R. Warner* v. *Eli Lilly & Co., supra; Upjohn Co.* v. *Schwartz, supra; Smith, Kline & French Laboratories* v. *Clark & Clark, supra.*[80] Petitioners do not contend that it would be absolutely impossible to sell these drugs in different capsule colors. Petitioners' grievance is that they should not in the first instance be burdened with the significant competitive disadvantage of marketing a product whose first reception in the hands of the ultimate consumer leads that consumer to the erroneous (if not anxiety-producing and irreversible) conclusion that a mistake has been made in filling the prescription.

The infringement of petitioners' rights is particularly severe where, as here, patient association of color with therapeutic effect is developed during the lifetime of a patent monopoly. Upon expiration of the patent, petitioners should be entitled to the full enjoyment of the product as it enters the public domain. Since capsule-color is rightly or wrongly regarded by consumers as being associated with therapeutic efficacy, the color here is not mere trade dress, but functions at least in the patient's mind as an integral part of the product itself. The prohibition on copying capsule colors thereby impermissibly extends a significant aspect of the former patent monopoly. *Kellogg Co.* v.

80. In *Ives* II, Judge Friendly suggested that this Court's approach in *Warner v. Lilly* and *Kellogg Co. v. National Biscuit Co.*, could be appropriate here. *Ives* II at Pet.App. 53a. For an example of supplemental labeling which could eliminate the so-called mislabeling problems, *see* Pl.Ex. 82S, J.A. 695a. Additionally, in *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F.Supp. at 422-423, the court granted preliminary injunctive relief, but refused to extend it across the board to prohibit sales to dispensing physicians. Here, a blanket injunction was authorized, prohibiting sale to even institutional accounts and federal and state governments, even though there can be no opportunity for illegal substitution or mislabeling.

National Biscuit Co., supra; Singer Mfg. Co. v. *June Mfg. Co.*, 163 U.S. 169, 185 (1896). *See also Zangerle*, 133 F.2d at 269. It is the exclusive patent monopoly which gives the brand-name company the opportunity to develop color as an associational factor in the minds of patients.

The essence of the error in the *Ives* IV opinion lies in its utilization of the trademark laws as a means toward the end of creating a new, absolute, and perpetual property right in capsule colors. *Ives* IV thus turns the law of trademarks on its head. When this Court in *Sears* and *Compco* referred to "federal statutory protection" as a permissible basis for prohibiting copying, it did not intend that §32 of the Lanham Act could be so broadly construed as to effectively make color an automatic property right incident to a registered trademark. The public policy factors identified in those decisions should apply with no less force to the interpretation of federal statutes than to a restriction on state laws of unfair competition. If state laws of unfair competition may not, under *Sears* and *Compco*, prohibit copying where the federal laws have spoken and declined to do so, then those decisions may not be bypassed by the expedient holding that the trademark laws can accomplish the very same result.[81]

In *Goldstein* v. *California*, 412 U.S. 546, 571 (1973); and *Kewanee Oil Corp.* v. *Bicron Corp.*, 416 U.S. 470, 479-480 (1974), the majority opinions emphasized that it was not the intention of this Court to abandon the underlying principles of *Sears* and *Compco*. *See also Ives* II at Pet.App. 43a-45a. Petitioner Inwood respectfully requests that unless *Sears* and *Compco* are now to become devoid of any meaning, the Court should definitively reconfirm their validity be reversing the ruling of the Second Circuit.

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81. In effect, *Ives* IV reads the state law doctrine of contributory trademark infringement into §32 as a means of escaping the strictures of *Sears* and *Compco*.

CONCLUSION

Petitioner Inwood respectfully submits that the judgment of the Court of Appeals for the Second Circuit be reversed, and that the judgment of the District Court in *Ives* III, dismissing the complaint, be reinstated.

Dated. New York, New York
November 27, 1981

Respectfully submitted,

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